PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06 — A1

(11) International Publication Number: **WO 98/30173**

(43) International Publication Date: 16 July 1998 (16.07.98)

(21) International Application Number: PCT/US98/00027

(22) International Filing Date: 12 January 1998 (12.01.98)

(30) Priority Data:
08/782,114 13 January 1997 (13.01.97) US

(71) Applicant: GORE ENTERPRISE HOLDINGS, INC. [US/US]; 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714-9206 (US).

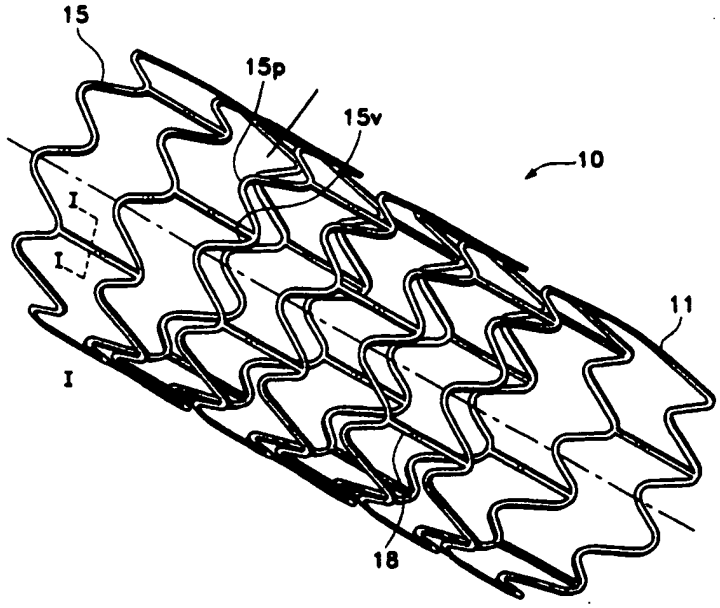
(72) Inventors: OGI, Darrell, H.; 951 Aberdeen Drive, Sunnyvale, CA 94087 (US). LAU, Lilip; 1132 South Sage Court, Sunnyvale, CA 94087 (US). KLENK, Alan, R.; 1126 Capri Drive, Campbell, CA 95008 (US).

(74) Agents: MARCUS, Michael, S. et al.; Morgan & Finnegan, L.L.P., 345 Park Avenue, New York, NY 10154-0053 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: LOW PROFILE SELF-EXPANDING VASCULAR STENT



(57) Abstract

A low-profile, self-expending vascular stent which is preferably cut from a thin tubing. The stent includes helical windings in a single helix, which are joined by bridges for longitudinal and radial strengthening.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

LOW PROFILE SELF-EXPANDING VASCULAR STENT

FIELD OF THE INVENTION

The present invention relates generally to implants for the treatment of bodily vasculature, ducts and the like. More specifically, the invention relates to low profile, vascular stents which are particularly useful for small diameter vascular applications.

BACKGROUND OF THE INVENTION

One method of treatment of diseased or otherwise damaged vasculature has traditionally been through the implantation of vascular stents and/or grafts to maintain patency of the vasculature. It has also been known to implant such devices in saphenous vein bypass grafts, either at the time of bypassing the coronary arteries, or at a later date when the saphenous vein graft becomes partially or totally occluded.

Although wire stents are generally acceptable for use in larger vessels, because of the generally reduced cross-sectional area available for blood flow in smaller vessels, the use of a wire stent often encroaches to an unacceptable extent within the lumen of the vessel, causing blood cell damage and possibly clotting. Similarly, stents which are formed of two or more overlapping helices present an encroachment problem into the lumens of smaller vessels, such as the carotid artery, coronary artery, etc. An additional problem with grafts fashioned from wire, is that it is difficult to reduce (e.g., through folding, radial compression or other reduction technique) the downsized versions to an acceptable profile for insertion through and placement in the smaller sized vessels.

Stents which are formed of a series of interconnected rings, with the rings being substantially perpendicular to the longitudinal axis of the stent are also known. Because of variations in the cross-sectional mass of this type of stent

along the longitudinal axis, this type of stent will tend to buckle in the weakest locations, e.g., generally in the locations where the rings are interconnected.

Many varieties of stents and stent-grafts have been described, but include one or more of the drawbacks discussed above. Pinchuk, U.S. Patent No. 5,163,958, discloses a helically wrapped, undulating wire stent coated with a layer of pyrolytic carbon. The wire stent includes a plurality of generally circumferential sections 22, which are formed from the same continuous, substantially helically wrapped, undulating length.

Lau et al., U.S. Patent No. 5,421,955, discloses an expandable stent made of a plurality of radially expandable cylindrical elements interconnected by one or more interconnective elements. The cylindrical elements may be individually formed from undulating elements. The entire stent may be made from a single length of tubing.

Schnepp-Pesch et al., U.S. Patent No. 5,354,309, discloses a stent including a memory alloy part which radially widens at a transition temperature that is above ambient temperature but below body temperature. The stent may include a helically wound wire, as shown in Figs. 4a-4b.

Leveen et al., U.S. Patent No. 4,820,298, discloses a flexible stent constructed of a helix made from medical thermoplastic. Adjacent loops of the helix are interconnected by elastomeric strands. This allows the stent to be stretched into a somewhat extended, linear configuration, and to resume its helical shape upon release of the stretching forces.

Lau et al., U.S. Patent No. 5,514,154, discloses an expandable stent made of a plurality of individual radially expandable cylindrical elements interconnected by one or more interconnective elements. The cylindrical elements may be individually formed from undulating elements. The entire stent may be made from a single length of tubing. The cylindrical elements include radially outwardly extending anchoring projections which may increase the profile of the expanded stent.

In summary, various stents, such as those discussed above, have been described with varying degrees of success. What has been needed and is addressed by the present invention, is a stent which has a high degree of flexibility for advancement through torturous pathways of relatively small diameter, can be readily expanded, and has sufficient mechanical strength to maintain patency of the lumen into which it is implanted, while minimizing the amount of lumenal encroachment to reduce the thrombosis risk.

SUMMARY OF THE INVENTION

The present invention involves an expandable stent which is relatively flexible along its longitudinal axis, while at the same time being provided with structures to increase the columnar strength thereof.

According to an embodiment of the present invention, a self-expanding stent includes a structure having helical windings forming a generally tubular shape, and bridges interconnecting the helical windings. Preferably, the bridges are helically arranged within the structure. Preferably, the stent is self-expanding. However, the embodiments are also included within the invention, including balloon-expandable stents.

The stent according to the present invention may be formed from a thin-walled tubing, Preferably the stent is cut from the tubing by laser cutting or by EDM (i.e., Electrical Discharge Machining), techniques which are known in the art.. However, various etching techniques may also be used. The thin-walled tubing also contributes to the low profile of the stent..

The bridges may be circumferentially and substantially equiangularly located about the helix, with respect to one another. Preferably, the bridges are located at an interval of about 2 to 4 bridges per 360° of helical winding. More preferably, the bridges are located at an interval of about 3 bridges per 360° of helical winding.

The bridges may be formed as substantially straight bridges. Alternatively, at least one of the bridges (and as many as all of the bridges) may

include or act as a spring having a predetermined spring constant. The spring(s) may be formed as an undulating spring. Alternatively, the spring(s) may be formed as a leaf-spring or other equivalent spring mechanism providing a comparable spring constant.

Preferably, at least one spring is aligned in a direction substantially parallel to the longitudinal axis of the generally tubular shape.

The helical windings of the helical structure and the bridges may have substantially equal widths. Alternatively, the widths of one or more of the bridges may be varied to alter the flexibility of the stent. Preferably, alterations are done to reduce the widths of the bridges with respect to the width of the helical windings of the helical structure, so as to increase the flexibility of the stent.

Preferably, the windings of the helical structure undulate in a direction substantially parallel to the longitudinal axis of the generally tubular shape. The low profile, self-expanding stent of the present invention preferably includes a single helical structure having windings forming a generally tubular shape having a longitudinal axis, and the single helical structure is formed from a thin-walled tubing.

Also, the stent preferably includes bridges interconnecting the windings of the helical structure, and undulations in the windings. The undulations enhance the expandability of the stent. Additionally, the bridges may be aligned in a direction substantially parallel to the longitudinal axis of the generally tubular shape. Preferably, the bridges are circumferentially and substantially equiangularly located about the helix, with respect to adjacent ones of the bridges.

The bridges may be helically arranged in the structure. Preferably, the bridges are positioned to form a ratio of about 3 bridges per 360° of windings. The stent may further include asymmetrical undulations in at least one of the helical windings, to compensate for uneven expansion which occurs due to the helical nature of the stent.

Other features and advantages of the present invention will become more apparent from the following detailed description of the invention, when read in view of the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a first embodiment of a stent embodying features of the present invention;

Fig. 2 is a cross-sectional view of a bridge taken along line I-I in Fig. 1;

Fig. 3 is a plan view of a flattened section of a stent according to the first embodiment, which illustrates the interrelationship between the undulating, helical pattern and the interconnecting bridges of the stent shown in Fig. 1;

Fig. 4 is a plan view of a flattened section of a stent according to a second embodiment, which illustrates the interrelationship between the undulating, helical pattern and the interconnecting bridges of the second embodiment;

Fig. 5a is a partial view of a stent embodying a variation of a bridge to interconnect adjacent undulations;

Fig. 5b is a partial view of a stent embodying a second variation of a bridge to interconnect adjacent undulations;

Fig. 5c is a partial view of a stent embodying a third variation of a bridge to interconnect adjacent undulations;

Fig. 5d is a partial view of a stent embodying a fourth variation of a bridge to interconnect adjacent undulations;

Fig. 6 is a plan view of a flattened section of a stent according to a third embodiment;

Fig. 7 is a plan view of a flattened section of a stent according to a variation of the third embodiment shown in Fig. 6;

Fig. 8 is a plan view of the stent shown in Fig. 7 after expansion of the same;

Fig. 9 is a plan view of a flattened section of a stent according to a fourth embodiment of the present invention;

Fig. 10 is a partial flattened section of a stent according to an embodiment similar to that shown in Fig. 9;

Fig. 11 is a partial flattened section of a stent formed with the same undulating pattern as the stent shown in Fig. 10, but in a ring configuration as opposed to a helical configuration, for comparison purposes;

Figs. 12a, 12b and 12c are views of preferred apparatuses for preparing for deployment and deploying a stent according to the present invention;

Figs. 13a, 13b, 13c, 13d, 13e and 13f show various stages of preparation for deployment, and deployment of, a stent according to the present invention; and

Figs. 14a, 14b and 14c show another arrangement for deploying a stent according to the present invention, at various stages of deployment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 illustrates a self-expanding stent constructed according to principles of the present invention. For use in relatively small diameter vessels, (e.g., carotid artery, coronary artery, saphenous vein graft), a simple downsizing of available stents which have been used for larger vessels has been generally unsatisfactory for use in implantation. For example, when a known design using nitinol wire and expanded polytetrafluoroethylene was reduced in size (particularly in the diameter dimension), the radial stiffness decreased below an acceptable lower limit.

The flexibility of the stent facilitates delivery of the stent through torturous body lumens, including, but not limited to coronary arteries, carotid arteries and saphenous vein grafts, where, in addition to being torturous, the vessel diameters are small.

In Fig. 1, self-expanding stent 10 generally comprises a continuous mesh pattern of sinusoidal or undulating member 15 formed into a helical pattern of helical windings to form substantially cylindrical, tube-shaped structure 11. The undulating member undulates to form bends 15p and 15v which are generally oppositely oriented in the direction of the longitudinal axis of cylindrical structure 11. The helical windings formed by the undulating member are joined by bridges

18 to provide the stent with columnar strength and radial strength, and also stability to minimize changes in the length of the stent upon expansion thereof. Bridges 18 also provide improved kink resistance upon bending of the stent 10, and resist bowing of the stent when implanted to bridge an aneurysm, for example. Helical stents which lack bridges are more susceptible to columnar compression and buckling. This problem is particularly noted in the treatment of aneurysms, where the stent or stent-graft is positioned to span the enlarged section forming the aneurysm. A stent without bridges often buckles due to the forces applied by the blood flow through the upstream end of the stent, which tend to act locally against the column strength of that end. The result is buckling of the central portion of the stent or stent-graft, such that the stent or stent-graft follows the contour of the aneurysm. Ultimately, the upstream end of the stent or stent-graft can be pulled out of the aneurysmal neck and into the aneurysmal sac, thereby allowing the blood flow to bypass the stent or stent-graft altogether. This results in total failure in the case of a stent-graft, since hydraulic isolation of the aneurysmal sac has been lost at this point.

Bridges 18 increase the axial stiffness and columnar strength of stent 10, as noted above. The forces applied by the blood flow through the upstream end of stent 10 are axially distributed along the stent 10 through the bridges 18. Thus, even when the stent 10 spans an aneurysm, some of the force of the blood flow through stent 10 will be transferred to the distal end of stent 10, on the opposite end of the aneurysm. Since the distal (downstream) end will also be at least in frictional contact with the vessel into which the stent is implanted, opposing forces to the blood flow can be generated at both the upstream and downstream ends of stent 10. This decreases the overall tendency to push the upstream end down along the vessel pathway and further reduces the tendency of the graft to move into the site of the aneurysm and follow the path of the expanded vessel. Even if some buckling does occur, the bridges 18, having a tendency to keep the axial spacing of the helical turns at a constant, act as springs in this situation,

storing energy which then acts to restore the stent to an unbuckled state. Stents without bridges have a much reduced ability in this regard.

The number of bridges 18 in a stent should be kept to an acceptable minimum to enable the profile of the stent to be minimized during delivery. Preferably, bridge configurations forming a ratio of about two to four bridges per helical turn (i.e., 360°) are believed to be acceptable, with the preferred configuration being a ratio of about three bridges per helical turn as shown in Fig. 3, for example. The bridge configuration of three bridges per helical turn provides an offset arrangement of the bridges between adjacent windings or turns. Such an arrangement maintains the axial bending flexibility of the stent in virtually all directions, which is important for placement through torturous pathways.

The bridges 18 are preferably interconnected between adjacent bends 15p and 15v of the undulating helical turns in order to prevent shortening of the stent during the expansion thereof, see Figs. 3 and 4. It is noted however, that such a configuration is not absolutely necessary for length maintenance of the stent during expansion, and that the length can be substantially maintained as long as the bridges 18 are interconnected between the same corresponding locations on adjacent windings throughout the stent. For example, the bridges could be interconnected between adjacent windings midway between bends on each adjacent winding, with consistent corresponding placement of the remaining bridges. It is further noted that although winding is preferred to provide adjacent bends 15p and 15v (i.e., "in-phase" winding), other winding configurations are also possible. For example, helical windings may be arranged so that bridges longitudinally align with and connect adjacent bends 15p and 15p ("out-of-phase" winding). Other winding arrangements are also possible.

Preferably, the entire structure of the stent is formed from a thin-walled tube. This construction minimizes the wall thickness and lumenal encroachment of the stent, within the lumen of the vessel into which the stent is placed. At the same time, radial and longitudinal strength are maintained, without sacrificing

flexibility or delivery profile. This minimizes the risks of blood cell damage and thrombosis associated with disruption of the blood flow profile.

The stent may be made by many different methods, including known chemical etching techniques and preferably, by laser cutting (e.g., Nd:Yag) from the tubing. Another preferred method of making stents according to the present invention is by Electric Discharge Machining (i.e., EDM), a technique known in the art. A preferred method of etching includes coating a thin-walled tubular member, such as nickel-titanium tubing, with a material which is resistive to chemical etchants, and then removing portions of the coating to expose the underlying tubing which is to be removed, but leaving coated portions of the tubing in the desired pattern for the stent so that subsequent etching will remove the exposed portions of the metallic tubing, but will leave the portions of the tubing which are to form the stent relatively untouched. The etchant-resistive material may then be removed from the stent by means of a machine-controlled laser according to known methods.

Preferably the stent undergoes a finishing process of electrochemical polishing by any of a number of techniques known in the art. Although such polishing reduces the overall dimensions of the members of the stent, and thereby weakens the stent with regard to its pre-polishing characteristics, this effect is overcome by simply "designing in" the additional dimensions of the material to be removed by electrochemical polishing, so as to end up with a stent having the desired dimensions and strength characteristics. Advantages obtained from the electrochemical polishing are that a smoother surface results, thereby reducing thrombosis, reducing the resistance to blood flow, making the stent more biocompatible. Electrochemical polishing also enhances the fatigue resistance of the stent and reduces the risk of balloon rupture in cases of stents which are not self-expandable but require expansion using a balloon catheter. Additionally, a smoother surface enables a lower friction with a funnel which is used to compress the stent, as discussed below, thereby rendering compression of the stent easier.

The tubing may be made of suitable biocompatible material such as stainless steel, titanium, tantalum, Elgiloy(a Co-Cr alloy), superelastic NiTi alloys (e.g., "nitinol"), and high strength thermoplastic polymers. The preferred materials are NiTi alloys and particularly "binary nitinol" (i.e., 50% Ni and 50% Ti by weight).

The desired pattern can be cut from a tubing having already been expanded and heat set according to known methods, or it can also be cut from a smaller diameter tubing, and then expanded and heat set at a larger diameter. When the stent is made of nitinol, the afore-described heat setting steps are included. However, as noted above, the stent may also be prepared from materials such as stainless steel (e.g. 316L stainless) and other materials which do not form a self-expandable stent but must be expanded by other methods such as expansion by a balloon catheter. In these examples, the heat set step is unnecessary and is not performed.

As shown in Fig. 2, the cross-sectional configuration of the bridges 18, as well as the undulating member 15 which has the same cross-section in this embodiment, is rectangular. This configuration provides greater radial rigidity for a given wall thickness, compared to the circular cross-section which is provided by a wire stent. Consequently, for a given radial strength, the stent formed from a thin radial tubing according to the present invention can be formed significantly thinner than a stent formed from wire, thereby affording a lower intralumenal profile and less impedance of blood flow, in addition to the other advantages discussed above. It is noted that the thicknesses of the undulating member and bridges are substantially equal to each other in all embodiments of the instant invention, although the comparative widths of the same may vary.

The greater radial rigidity, discussed above, also allows the stent to be formed as a single helical structure, which greatly reduces the intralumenal profile. The stent has no anchoring projections in its expanded configuration, which further contributes to the low profile of the stent. The bridges make the stent longitudinally stiffer than a helical structure which lacks bridges, and also

ensure that there is significantly less length change of the stent upon expansion of the same.

Additionally, the strength, flexibility and expandability of the present invention eliminate the need for secondary attachment methods, such as sutures, which also add thickness and thereby increase the lumenal encroachment and roughen the lumenal surface to increase the disruption of the blood flow profile, or may adversely affect the delivery profile of a stent.

Further, it is believed that the helical stent according to the present invention can be compressed to a smaller delivery profile than can a stent formed of individual rings, or other ring type structure, as discussed below with regard to Figs. 10 and 11, and certainly smaller than a wire or double helix type configuration.

Additionally, the helix configuration according to the present invention has been found to be more flexible, particularly in the axial or longitudinal direction, than ring type stents. Still further, the rings in a ring type stent are independently expandable, which may lead to discontinuities in the expansion profile. In contrast, the helical stent according to the present invention is continuously expandable and therefor does not run the risk of forming discontinuities or "steps" upon expansion of the device, thereby resulting in a smoother lumen. This results in better hemodynamics through the stent when implanted, thereby reducing the risk of thrombosis.

Fig. 4 shows a plan view of a flattened section of a second embodiment of a stent according to the present invention. In this embodiment the bends 25p and 25v are notably sharper than those of the first embodiment, such that they approach angular peaks and valleys, as compared with the relatively curved bends 15p ,15v of the first embodiment (see Fig. 3). The embodiment of Fig. 4 affords a stiffer stent in the expanded state than that of Fig. 3. However, at the same time, the embodiment of Fig. 3 opens more evenly, leaving fewer irregularities and gaps in the expanded stent than does the embodiment of Fig. 4.

To provide additional control in the design of the flexibility of the stent, the construction of the bridges may be modified from the straight strut-type design 18, as shown by three examples 38a, 38b and 38c in Figs. 5a, 5b and 5c, respectively. It is noted that although the members 38a, 38b and 38c are shown in combination with the undulation members of the first and second embodiments of the present invention, the modified bridges may be applied generally to any of the embodiments disclosed herein, and to the invention in general.

In Fig. 5a, the bridge has been modified to form an undulating, spring type member 38a which affords more compressibility in the direction aligned with the longitudinal axis of the cylindrical stent . The bridge 38a also increases the bendability (i.e., reduces the bending strength) in radial directions. It is further noted that a stent could be specifically tailored for asymmetrical bending and strength characteristics by individually designing only predetermined bridges 18 as spring type bridges 38a. Thus, as few as zero or one of the bridges 18 could be formed as a spring bridge 38a, or as many as all of the bridges in a stent could be so formed. Generally, it is preferred that all of bridges 18, or a symmetrical configuration of a portion of bridges 18 are formed as spring bridges 38a, so as to give symmetrical bending and strength characteristics. However, this is not always the case and the invention is not to be so limited.

Fig. 5b, shows a bridge which has been modified to form leaf-spring like member 38b, which also affords more compressibility in the direction aligned with the longitudinal axis of the cylindrical stent. Likewise, bridge 38b also increases the bendability (i.e., reduces the bending strength) in radial directions. Similar to spring bridge 38a, a stent could also be specifically tailored for asymmetrical bending and strength characteristics by individually designing only predetermined bridges 18 as spring type bridges 38b. Thus, as few as zero or one of the bridges 18 could be formed as a spring bridge 38b, or as many as all of the bridges in a stent could be so formed. Generally, it is preferred that all of bridges 18, or a symmetrical configuration of a portion of bridges 18 are formed as spring

bridges 38b, so as to give symmetrical bending and strength characteristics. However, this is not always the case and the invention is not to be so limited.

By making the stent more compressible with the aforementioned spring type designs, the folding or compression profiles of the resultant stents may be negatively effected. Fig. 5c shows a third alternative way to increase compressibility and flexibility without negatively effecting the folding or compression profile of the resultant stent. In this embodiment, one or more of the bridges is made more compressible and bendable by reducing the width 38w of bridge 38c. Thus, width 38w of bridge 38c is less than the width of undulating member 15,25, etc. Not only does this configuration not negatively effect the compression or folding profile of the resultant stent, it may actually positively effect such profiles, and also reduces the overall weight of the resultant stent. As with the embodiments of Figs. 5a and 5b, as few as zero or one of bridges 18 could be formed as a narrow bridge 38c, or as many as all of the bridges in a stent could be so formed. Generally, it is preferred that all of bridges 18, or a symmetrical configuration of a portion of bridges 18 are formed as narrow bridges 38c, so as to give symmetrical bending and strength characteristics. However, this is not always the case and the invention is not to be so limited.

It is further noted that the embodiment of Fig. 5d could also be employed to increase the strength of the resultant stent when in the expanded position. This would be accomplished by increasing the width of one or more bridges 18 to form wide bridges 38d. Although this is generally not the preferred embodiment of the present invention, it is an option which is available to the stent designer. Of course, the entire structure of the stent, including the undulating member and the bridges may be widened as another option for increasing the strength of the stent. The width ratio of the bridges to undulating members ranges generally from about 0.5:1 up to about 1.5:1, with preferred ratios being about 1:1 or less.

Fig. 6 shows a third embodiment of the inventive stent, which includes a pattern that is preferably cut into a smaller diameter tubing, and then expanded to a larger functional diameter and heat set at the larger diameter to give it self-

expanding properties. For example, the pattern of the embodiment shown in Fig. 6 could be cut into a nitinol tube having about a 2.0 mm diameter, expanded to about a 4.0 mm diameter and then heat set.

In this embodiment, prior to expansion, it is noted that bends 35p,35v are substantially rounded so as to effectively form semicircles. The members 35m interconnecting the bends 35p, 35v are substantially aligned with the longitudinal axis of the cylindrical tubing from which the stent is cut. Upon expansion, however, the members 35m become substantially transverse to the longitudinal axis of the cylindrical shape of the stent, as will be discussed and shown below with regard to the following embodiment.

Another variation from the previous embodiments, is that although bridges 18 are preferably interconnected between adjacent bends 15p,15v of the undulating helical turns in order to prevent shortening of the stent during the expansion thereof, the particular bends to which bridges 18 are connected are slightly modified from the unconnected bends 15v, such that the connected valleys 15v' form two substantial semicircles with the bridge 18, one on each side of bridge 18. This variation allows a more even expansion of members 35m out from valley 35v' with respect to bridge 18 upon expansion of the cylinder.

It is to be noted that in this and all other embodiments, the bend elements 15p and 15v are subject to a particular orientation of the stent as shown in the Figs. Accordingly, the elements 15p and 15v can be interchanged with regard to any of the embodiments described herein, as long as they are interchanged consistently throughout the entire description of the embodiment. Such an interchange would be tantamount to inverting the particular figure(s) referred to by the detailed description of that embodiment.

The helical nature of the stent designs according to the present invention dictates some anomalies in the resultant cylindrical structure of the final product, which may be addressed by the following further embodiments.

Fig. 7 shows a modification of the embodiment of Fig. 6 in which the end portions of the cylinder that form the stent have been modified , so that both ends

form "square ends", i.e., circles which are substantially perpendicular to the longitudinal axis of the cylindrical shape of stent 30'. In order to effectuate such "square ends", the lengths of the members connecting the bends 35p,35v(35v') are gradually increased to compensate for the pitch angle of the helix (e.g., see the progression of lengths: 35m, 35m', 35m",...). Additionally, any bridges which interconnect bends 35p,35v, which are also connected by lengthened members (35m', 35m" etc.) also must follow a progressive lengthening scheme (e.g., see 18, 18',...).

Fig. 8 shows stent 30' in the expanded state at which it is to be heat set. As noted with regard to the similar embodiment in Fig. 6, prior to expansion, the bends 35p,35v are substantially rounded so as to effectively form semicircles (see Fig. 7), and the members 35m, 35m', 35m",... interconnecting the bends 35p and 35v,35v' are substantially aligned with the longitudinal axis of the cylindrical tubing from which stent 30' is cut. Upon expansion, however, members 35m, 35m'...become substantially transverse to the longitudinal axis of the cylindrical shape of stent 30', while bridges 18, 18'... maintain a substantially parallel positioning to the longitudinal axis. Thus, the bridges maintain their maximum potential for longitudinally strengthening stent 30'.

Another anomaly dictated by the helical nature of the stent structures described above, is that some members 35m" throughout the stent necessarily have somewhat longer lengths compared to the standard length member 35m. This is due to the nature of the helical windings which progressively move away from the previous adjacent helical winding, and thus require some longer members to compensate for the pitch angle of the helix and maintain a standard bridge length. Because not all of the member lengths are equal, upon expansion of the stent, some uneven or unequal gaps between bridges 18 and members, e.g., 35m, 35m" also occur. In order to compensate for these abnormalities in spacing, stent 40 shown in Fig. 9, includes asymmetrical members 44m and 45m which connect to one end of each bridge on opposite sides thereof. Because member 44m has a greater degree of curvature than member 45m, it allows for a greater

degree of expansion on the side of member 44m, which compensates for the unevenness in expansion caused by the helical windings.

As mentioned above, it is believed that the helical stent according to the present invention can be compressed to a smaller delivery profile than can a stent formed of individual rings, or other ring type structure. Fig. 10 shows a flattened section 70 of a helical stent like the embodiment shown in Fig. 9, wherein the stent has been cut longitudinally parallel to the longitudinal axis and flattened out into a substantially planar structure. Fig. 11 shows a flattened section 80 of a stent formed with the same undulating pattern as the stent shown in Fig. 10, but in a ring configuration as opposed to a helical configuration, for comparison purposes.

Imaginary lines 75 and 85 are drawn perpendicular to the longitudinal axes of the stent portions 70 and 80, respectively. The total number of structures (including bridges and members) which are intersected by the line 75 is 11 as compared to 13 structures which are intersected by line 85. The difference is explained by the helical structure of Fig. 10, which more continuously distributes the mass of the structure along the entire length of the stent. On the other hand, the mass of the ring type stent shown in Fig. 11 is more concentrated in the rings, with a lower concentration in the areas connecting between the rings. The minimum profile to which a stent can be reduced is limited by that portion of the stent which has the largest diameter after reduction of the stent for delivery. Thus, the profile of the ring type stent is expected to be larger than the helical stent since the largest sections of the ring type stent include 13 structures within the radius thereof, as compared to 11 within the radii of the sections throughout the helical stent.

Figs. 12a-12c show various equipment used in the preferred method for preparing a stent according to the present invention for deployment as well as for deploying the stent. Preferably, a self-expanding stent is radially crushed or compressed to have a reduced diameter for introduction into a vessel into which it is to be implanted. Alternatively, the stent may be folded and held in the folded state during the introduction phase, or a stent may be formed in a smaller

diameter, introduced into the vessel and then expanded by a balloon catheter or the like.

Preferably, a self-expandable stent is compressed by drawing the same through a funnel, to be discussed in detail below. The stent is held in the compressed state within a sleeve. Within the sleeve is placed a catheter 90, as shown in Fig. 12a. Catheter 90 functions to guide the stent and the entire apparatus through the vessel and to the implant site. Catheter 90 includes an enlarged diameter portion 124 which has an outside diameter larger than the inside diameter of the stent in its compressed state. Thus, enlarged diameter portion 124 functions to prevent the compressed stent 95 from sliding in a direction toward the proximal end of the catheter 90. The distal end of catheter 90 is adapted to receive "olive" 91. The outside diameter of olive 91 is larger than the inside diameter of the stent in its compressed state. Thus, affixation of olive 91 to the distal end of catheter 90, functions to prevent any tendency of the compressed stent to slide off the distal end of catheter 90 prior to implantation of the stent. Catheter 90 is preferably made of polyimide, but other known equivalent materials suitable for such purpose, may be substituted.

In order to apply sufficient pulling force to draw stent 95 through a funnel for compression thereof, filaments 96 are preferably woven through the members of stent 95 and formed into loops 97 and 98 extending from opposite end of stent 95, as shown in Fig. 12b. Filaments 96 are preferably commercially available sutures and preferably are CV-7 GORETEX sutures (manufactured by W. L. Gore). Of course, other gauges of suturing materials may be substituted, and other materials may be used as well, e.g., stainless steel wire, various polymeric filaments, etc. Filaments which are preferably thicker than filaments 96 are next looped through loops 97 and 98 to form a short pulling line 100 and a long pulling line 99, respectively. Pulling lines 99 and 100 are preferably formed from 5.5 gauge suturing materials, but other substitutes may be used, similar to the substitutes for filaments 96.

Sleeve 110 (Fig. 12c), like catheter 90, is preferably made of polyimide, but other known equivalent materials for such purpose may be substituted. The inside diameter of sleeve 110 is designed to be substantially equal to, or slightly larger than the intended outside diameter of stent 95 when in the compressed state. The proximal end of sleeve 111 flares out to an enlarged control handle 112 which can be grasped for retraction of the sleeve during deployment of stent 95.

After interweaving filaments 96 with stent 95 and connecting pulling lines 99 and 100, the preparation for deployment of stent 95 continues by axially aligning funnel 130 with sleeve 110, as shown in Fig. 13a. Funnel 130 is preferably formed of stainless steel, however, other relatively rigid materials which exhibit a low friction characteristic with regard to the stent materials may be used. For example, high density thermoplastics or thermosetting polymers could be used, with or without a low friction inner coating material applied thereto. Other metals such as titanium, tantalum, silver and gold may also be used. Any other materials known to be sufficiently nonimmunogenic, and which would exhibit sufficient strength to compress the stents according to the present invention, while also exhibiting a low friction characteristic with regard to the present stent materials, may be used.

Funnel 130 has a distal inside diameter 131 that is slightly larger than the outside diameter of stent 95 when in the uncompressed state. The inside diameter of funnel 130 gradually tapers from distal inside diameter 131 to a proximal inside diameter 132 which is slightly less than the inside diameter of sleeve 110, so that when stent 95 is pulled through funnel 130, the resultant compressed stent 95 slides easily into sleeve 110 which then maintains stent 95 in the compressed state.

Upon axial alignment of funnel 130 with sleeve 110, long pulling line 99 is then threaded through funnel 130 and sleeve 110 to protrude from the proximal end of sleeve 110 as shown in Fig. 13a. Stent 95 is then axially aligned with funnel 130 and maintained in this position by applying a slight pulling force via pulling line 99. Short pulling line 100 may be used to assist in manipulation of

stent 95 to ensure proper axial alignment thereof. By gradually and steadily increasing the pulling force on pulling line 99, stent 95 begins to be compressed as it is pulled along the continuously decreasing inner diametrical surface of funnel 130.

As the stent is pulled through the proximal end (i.e., proximal inside diameter) of funnel 130 it has attained an outside diameter which is slightly smaller than that of its final compressed state, and thus slides relatively easily into sleeve 110. Once the stent has been pulled completely into sleeve 110, as shown in phantom in Fig. 13b, the pulling force is discontinued. Stent 95, upon entering sleeve 110, expands slightly to abut the inner circumference of sleeve 110 and assume the final compressed diameter. Withdrawal of filaments 96 from stent 95 can be accomplished in at least two different manners. Short pulling line 100 may be cut and withdrawn from engagement with loops 97. Afterwards, pulling line 99 is withdrawn from sleeve 110, drawing filaments 96 out along with it. Alternatively, pulling line 99 may be cut and withdrawn from engagement with loops 98. Afterward, pulling line 100 is withdrawn from funnel 130, drawing filaments 96 out along with it.

After removal of the pulling lines 99,100 and filaments 96, funnel 130 is removed, leaving stent 95 compressed within sleeve 110. Next, the proximal end of catheter 90 is inserted through the tubular opening of compressed stent 95 and sleeve 110 as shown in Fig. 13c. Catheter 90 is slid entirely through sleeve 110 until enlarged diameter portion 124 abuts against compressed stent 95 and the distal end of catheter 90 becomes substantially aligned with the distal end of sleeve 110.

Olive 91 is next fixably attached to the distal end of catheter 90, as shown in Fig. 13d, to abut against the distal end of sleeve 110 so as to prevent movement of compressed stent 95 in the distal direction. Olive 91 is preferably adhesively bonded to catheter 90 using any of a variety of well-known, biocompatible adhesives which would be readily known and available to those of ordinary skill in the art. Alternatively, olive 91 could be screw threaded, heat bonded, spin

welded, or fixed to catheter 90 by a variety of other known techniques which would be equivalent for purposes of this invention. At this stage, the apparatus is fully assembled for insertion into a vascular site or bodily organ, for deployment of stent 95.

After the apparatus has been inserted to the desired implantation site, the operator grasps both control handle 112 and catheter 90 to begin the deployment of stent 95. The operator maintains the position of catheter 90 while steadily and slowly withdrawing control handle 112 away from the site of implantation. As a result, enlarged diameter portion 124 maintains the stent 95 in the desired location by its abutment with the proximal end of stent 95, as sleeve 110 is slid with respect to stent 95 and gradually withdrawn from engagement therewith. Thus, stent 95 remains in the desired implantation site and is prevented from being dragged along with the sleeve 110 by enlarged diameter portion 124, upon withdrawal of sleeve 110 from the implantation site.

Fig. 13e shows that stent 95 self expands as sleeve 110 is withdrawn from contact therewith. Upon complete removal of contact between sleeve 110 and stent 95, the stent resumes its previous uncompressed configuration as shown in Fig. 13f, thereby abutting the walls of the vessel into which it has been implanted. The operator then begins to withdraw catheter 90, until catheter 90 and olive 91 are completely withdrawn from the organism into which the implantation is performed, to allow follow-up closure procedures to be carried out.

Figs. 14a-14c show an alternative arrangement used in preparation for deployment, and deployment of, a stent according to the present invention. In this embodiment sleeve 140 is not designed to extend from the implantation site all the way out of the organism for direct manipulation by the operator, as in the case of the embodiment discussed above. Rather, sleeve 140 is only slightly longer than stent 95 to ensure that stent 95 can be completely and reliably maintained therewithin in the compressed state. Sleeve 140 is preferably formed of polyimide, but substitute materials are applicable, just as discussed with regard to sleeve 110.

Catheter 150 is provided with both a distal olive 151 and a proximal olive 152 for maintaining the compressed stent in position prior to deployment. Stent 95 is compressed within sleeve 140, in much the same manner as described above with regard to sleeve 110. Catheter 150 is then inserted in much the same manner as described above with regard to catheter 90, and olive 151 is then connected in much the same manner as described above with regard to olive 91.

Catheter 150 further includes proximal transition 153 for transitioning the catheter from the distal portion of the catheter 154, which carries the sleeve 140 and the graft 95, and the proximal portion of the catheter 155, which is the rest of the catheter that is proximal to the proximal transition 153. A tether line or draw cord 156 is fixed to the proximal end 140a of sleeve 140. The tether line or draw cord (hereafter, tether line) 156 may be formed from stainless steel wire, high strength and biocompatible polymer fibers, or the like equivalents known in the art. Tether line 156 also is slidably fixed to proximal transition 153 at 153a, where tether line 156 passes internally of the proximal portion 155 of the small diameter catheter. Tether line 156 extends out the proximal end of the small diameter catheter 150 (not shown) for manipulation by the operator.

As shown in Fig. 14b, deployment of stent 95 begins when the operator has successfully located the distal end of the small diameter catheter 150, and thus stent 95, in the desired location. The operator then begins to steadily and gradually pull tether line 156, so as to retract sleeve 140 from its position around stent 95. Consequently, graft 95 begins to self-expand in a continuous manner as portions of the stent 95 are continuously freed. Olive 152 prevents the compressed proximal end of stent 95 from sliding with respect to the small diameter catheter 150, and thus prevents retraction of stent 95 along with sleeve 140.

Upon complete retraction of sleeve 140 and expansion of graft 95, the deployment apparatus, including small diameter catheter 150, sleeve 140 and tether line 156 can be withdrawn from the organism as a unit, for follow-up closing procedures.

Although the embodiments of the present invention have been described herein with reference to the accompanying drawings and the particular structures depicted therein, obviously many modifications and changes may be made by those of ordinary skill in the art without departing from the scope of the invention as defined by the claims which follow.

CLAIMS

What is claimed is:

1. A stent comprising:

a structure having helical windings forming a generally tubular shape having a longitudinal axis; and

bridges interconnecting said helical windings.

2. The stent of claim 1, wherein said bridges each interconnect a pair of said windings.

3. The stent of claim 1, wherein said structure is a single helical structure having said helical windings.

4. The stent of claim 1, wherein said bridges are aligned in a direction substantially parallel to said longitudinal axis of said generally tubular shape.

5. The stent of claim 1, wherein said stent lacks any anchoring projections when said stent is in an expanded configuration.

6. The stent of claim 1, wherein said bridges are helically arranged in said structure.

7. The stent of claim 1, wherein said helical structure is formed from a thin-walled tubing.

8. The stent of claim 7, wherein said single helical structure is laser cut from said thin-walled tubing.

9. The stent of claim 7, wherein said single helical structure is chemically etched from said thin-walled tubing.

10. The stent of claim 7, wherein said single helical structure is cut from said thin-walled tubing by EDM programming.

11. The stent of claim 1, wherein said bridges are circumferentially and substantially equiangularly located about said helix, with respect to adjacent ones of said bridges.

12. The stent of claim 10, wherein said bridges are positioned to form a ratio of about 2 to 4 bridges per 360° of said helical winding.

13. The stent of claim 12, wherein said bridges are positioned to form a ratio of about 3 bridges per 360° of said helical winding.

14. The stent of claim 1, wherein said bridges comprise substantially straight struts.

15. The stent of claim 1, wherein at least one of said bridges comprises a spring having a predetermined spring constant.

16. The stent of claim 15, wherein said spring comprises an undulating spring.

17. The stent of claim 15, wherein said spring comprises a leaf-spring.

18. The stent of claim 15, wherein said at least one of said bridges comprising a spring is aligned in a direction substantially parallel to said longitudinal axis of said generally tubular shape.

19. The stent of claim 1, wherein said helical structure and said bridges have substantially equal thicknesses.

20. The stent of claim 1, wherein said helical structure and said bridges have substantially equal widths.

21. The stent of claim 1, wherein at least one of said bridges comprises a width which is substantially less than a width of said helical structure.

22. The stent of claim 1, wherein said windings of said helical structure undulate in said direction substantially parallel to said longitudinal axis of said generally tubular shape.

23. The stent of claim 1, wherein said stent comprises a self-expandable stent capable of being compressed for delivery, and being self-expandable when removed from a compressive force.

24. The stent of claim 1, wherein said stent is expandable by application of force via a balloon catheter.

25. A low profile stent comprising:

a single helical structure having windings forming a generally tubular shape having a longitudinal axis, wherein said single helical structure is formed from a thin-walled tubing;

bridges interconnecting said windings of said helical structure; and

undulations in said windings, said undulations enhancing the expendability of the stent.

26. The stent of claim 25, wherein said bridges are aligned in a direction substantially parallel to said longitudinal axis of said generally tubular shape.

27. The stent of claim 26, wherein said bridges are circumferentially and substantially equiangularly located about said helix, with respect to adjacent ones of said bridges.

28. The stent of claim 25, wherein said bridges are helically arranged in said structure.

29. The stent of claim 28, wherein said bridges are positioned to form a ratio of about 3 bridges per 360° of said windings.

30. The stent of claim 25, further comprising asymmetrical undulations in at least one of said helical windings, to compensate for uneven expansion which occurs due to the helical nature of the stent.

31. The stent of claim 25, wherein said stent comprises a self-expandable stent capable of being compressed for delivery, and being self-expandable when removed from a compressive force.

32. The stent of claim 25, wherein said stent is expandable by application of force via a balloon catheter.

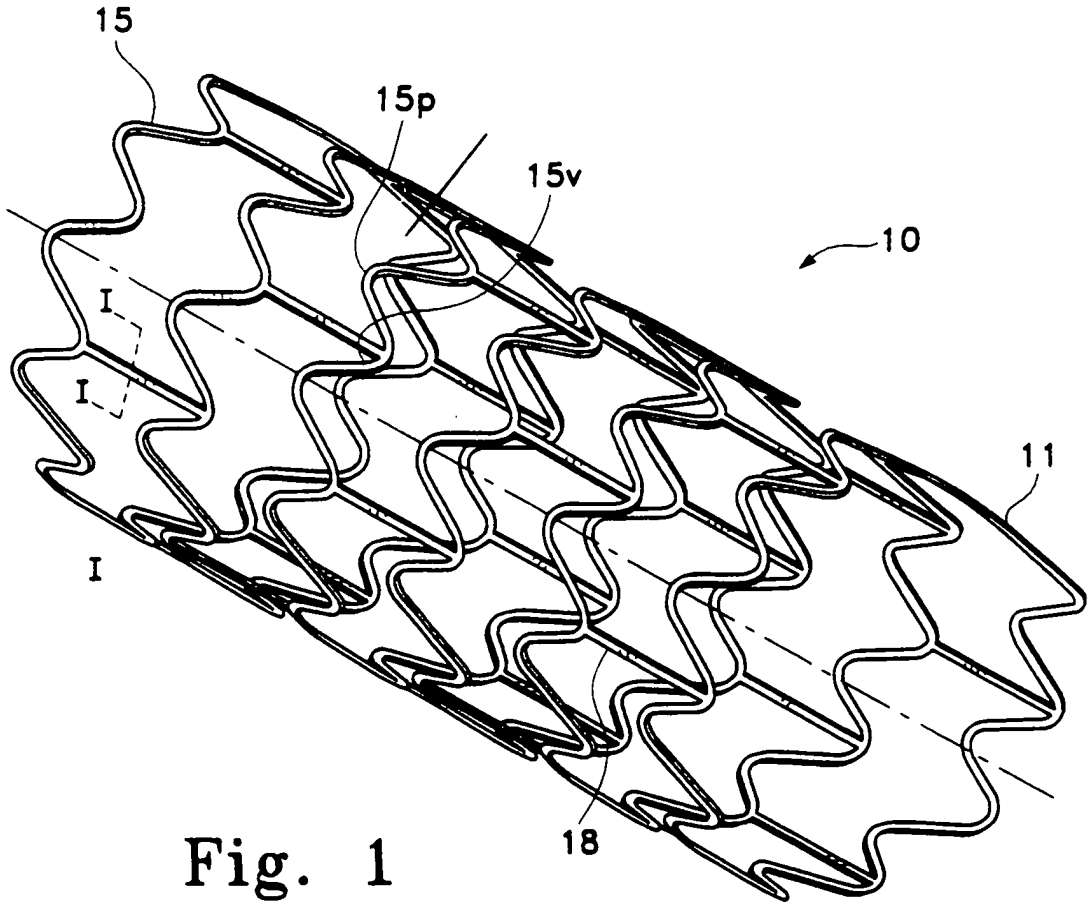


Fig. 1

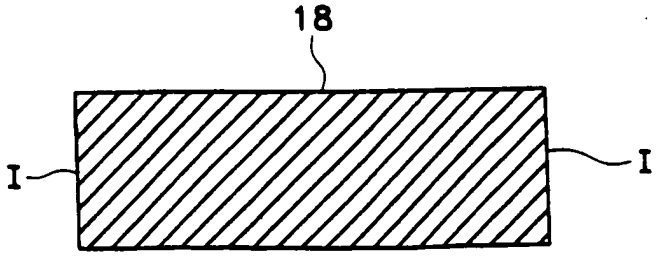


Fig. 2

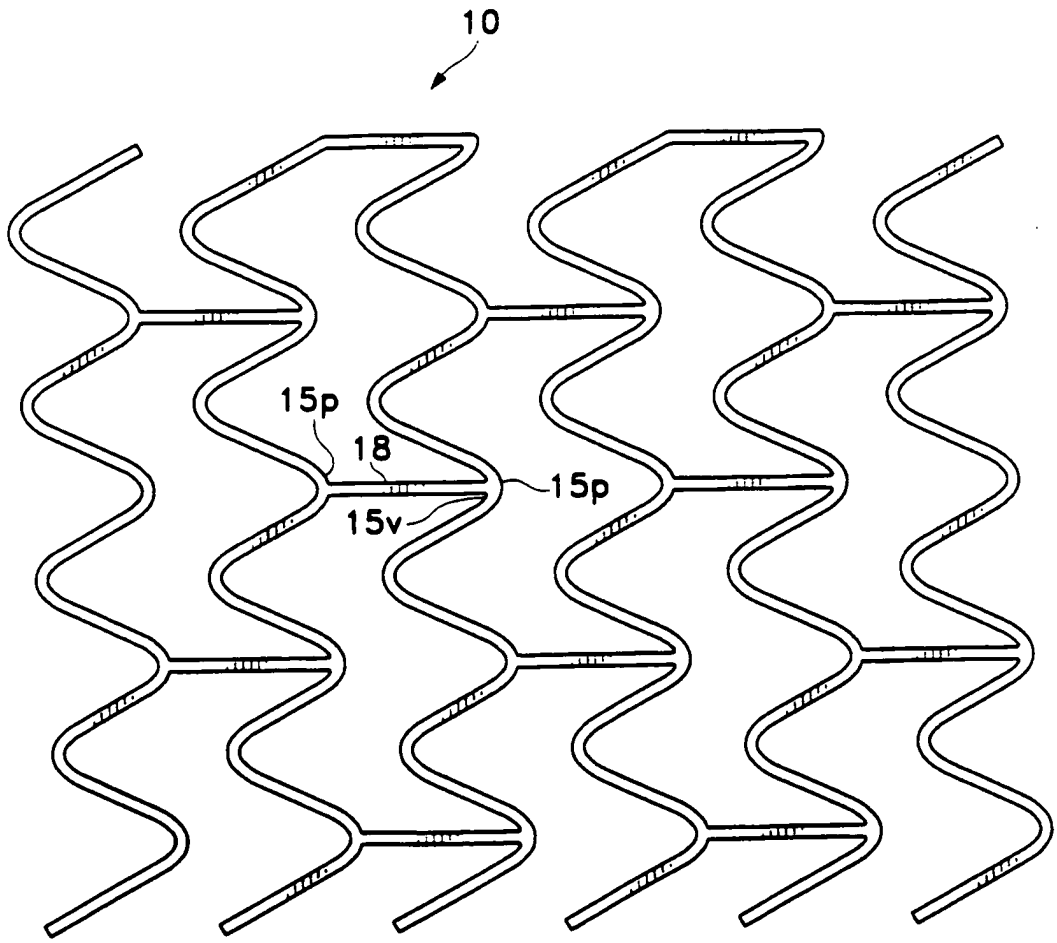


Fig. 3

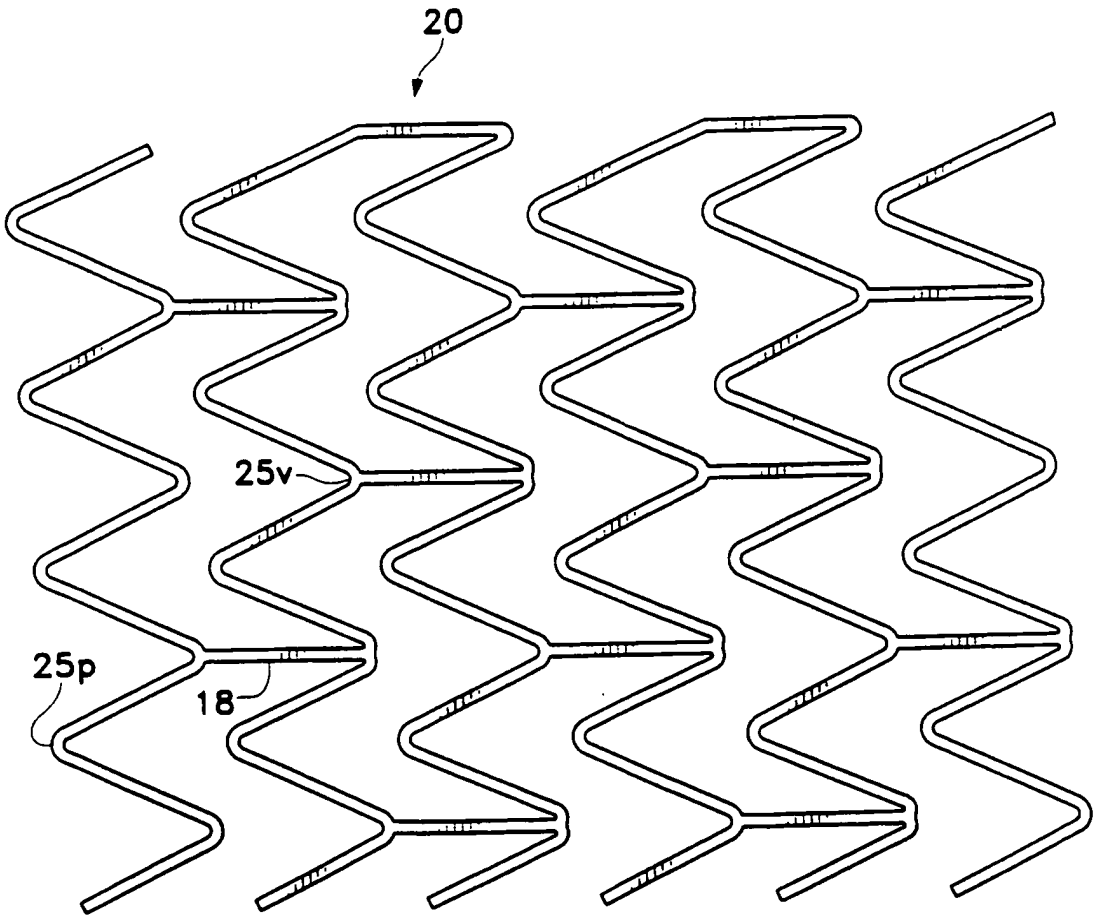


Fig. 4

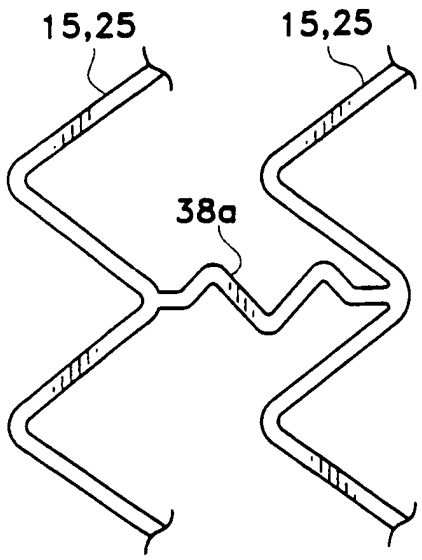


Fig. 5a

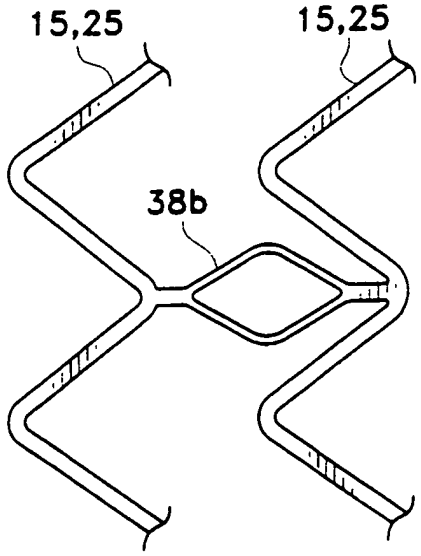


Fig. 5b

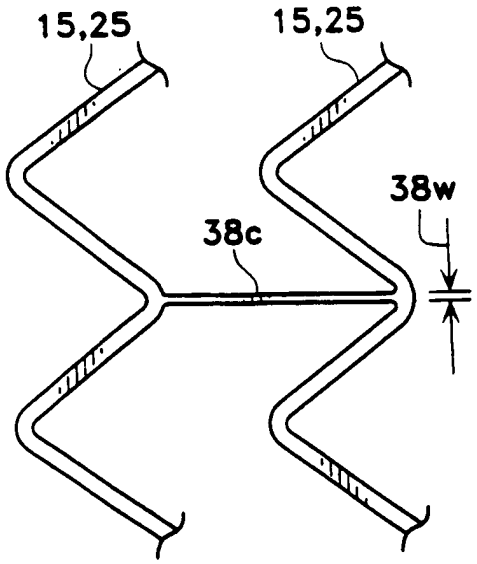


Fig. 5c

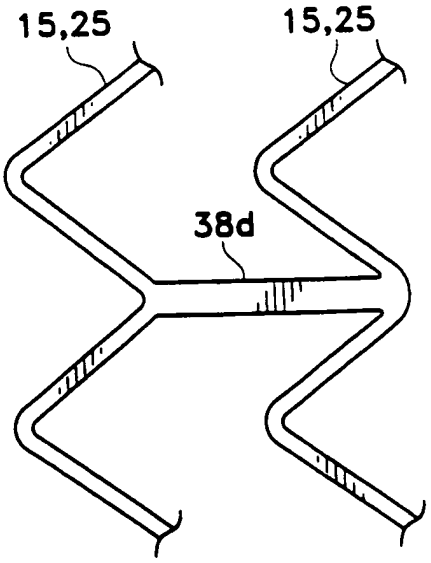


Fig. 5d

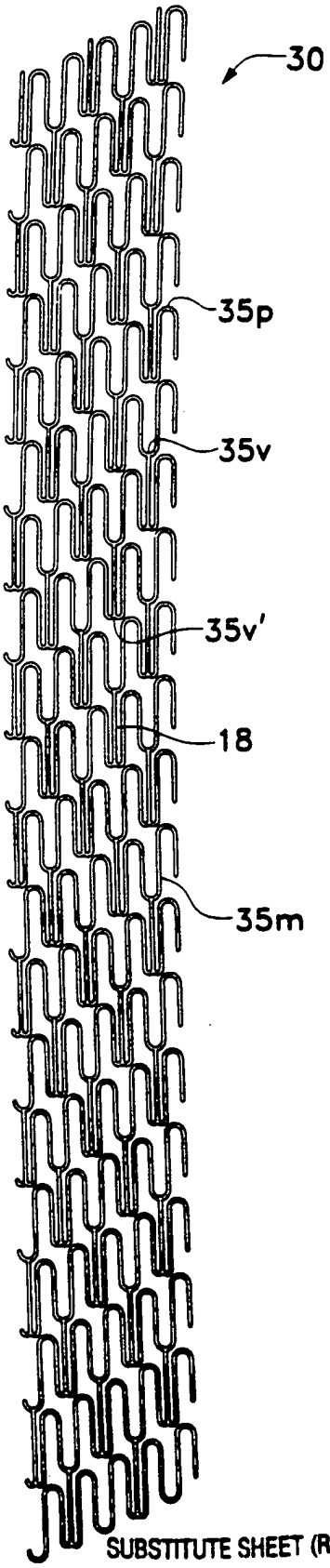


Fig. 6

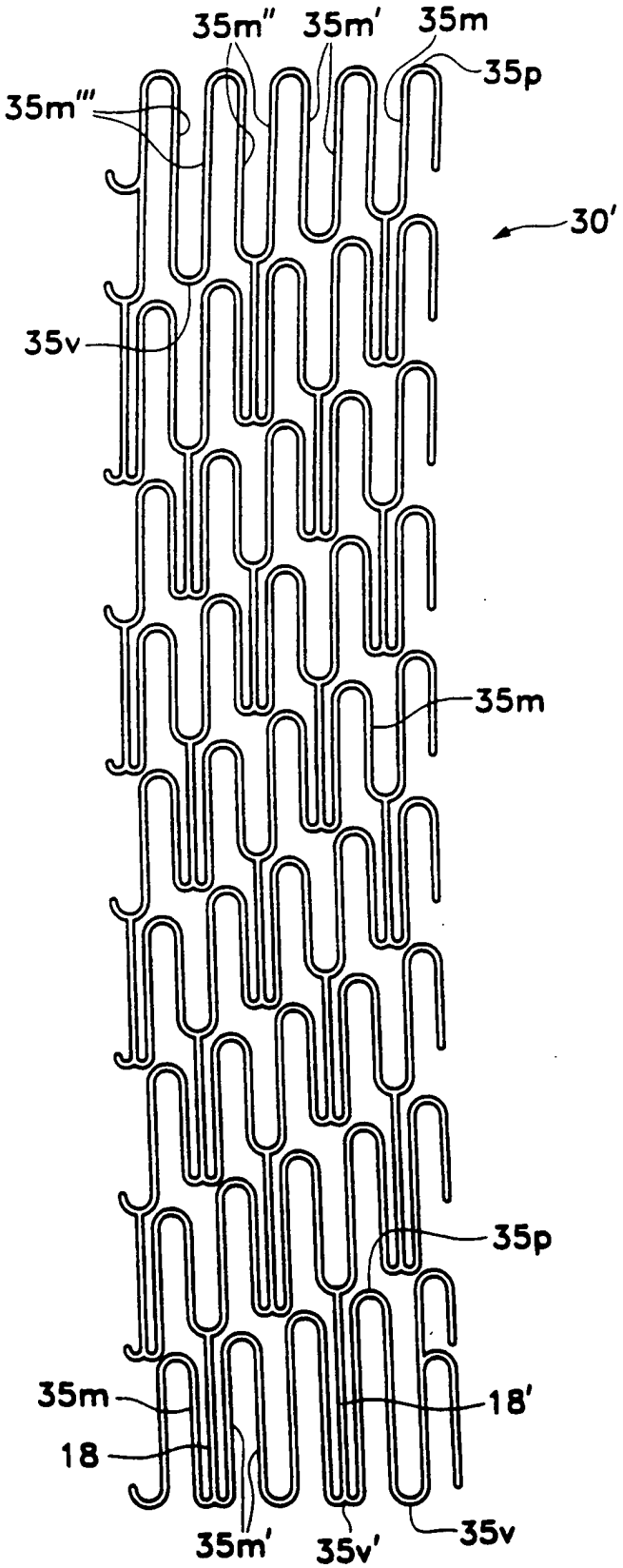


Fig. 7

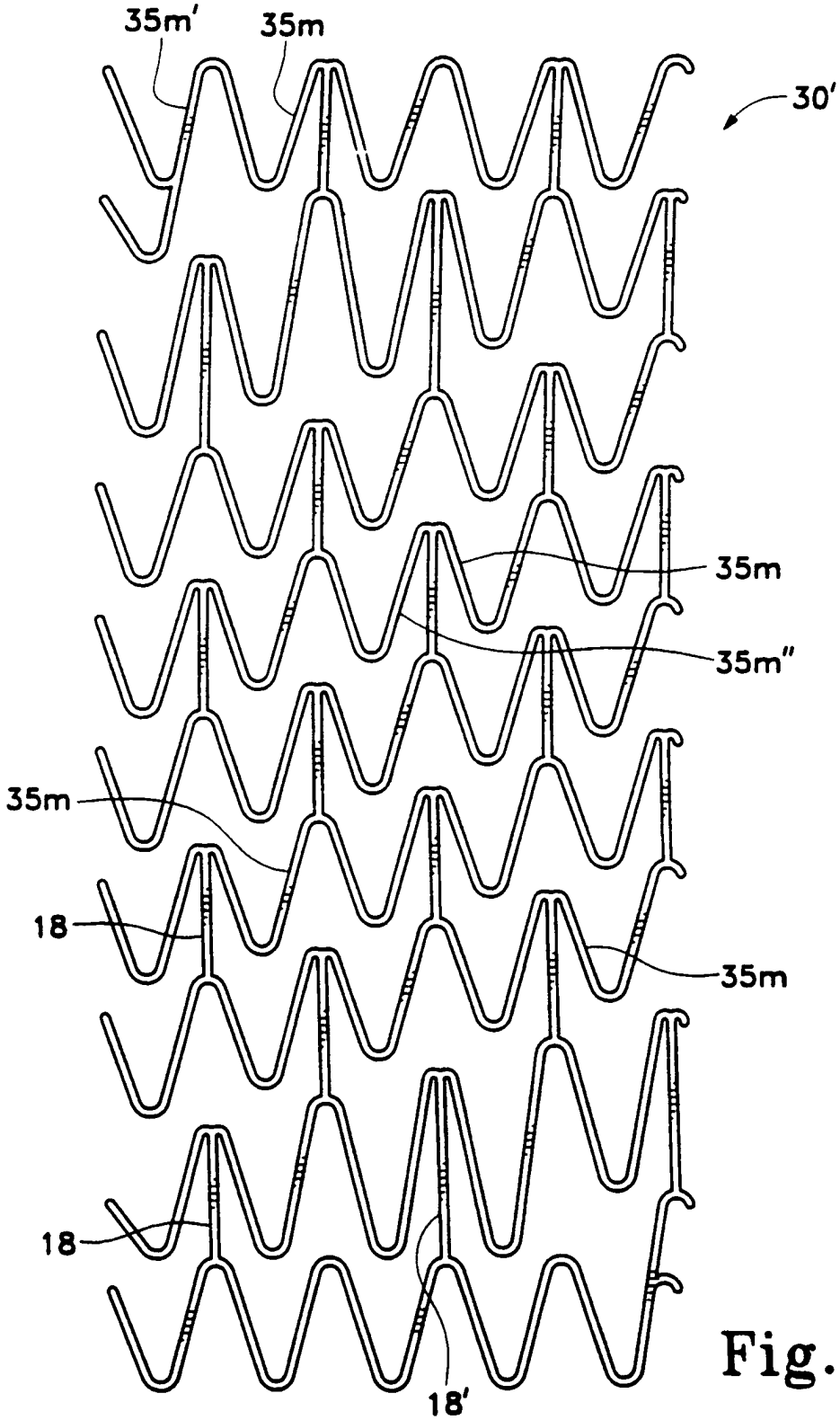


Fig. 8

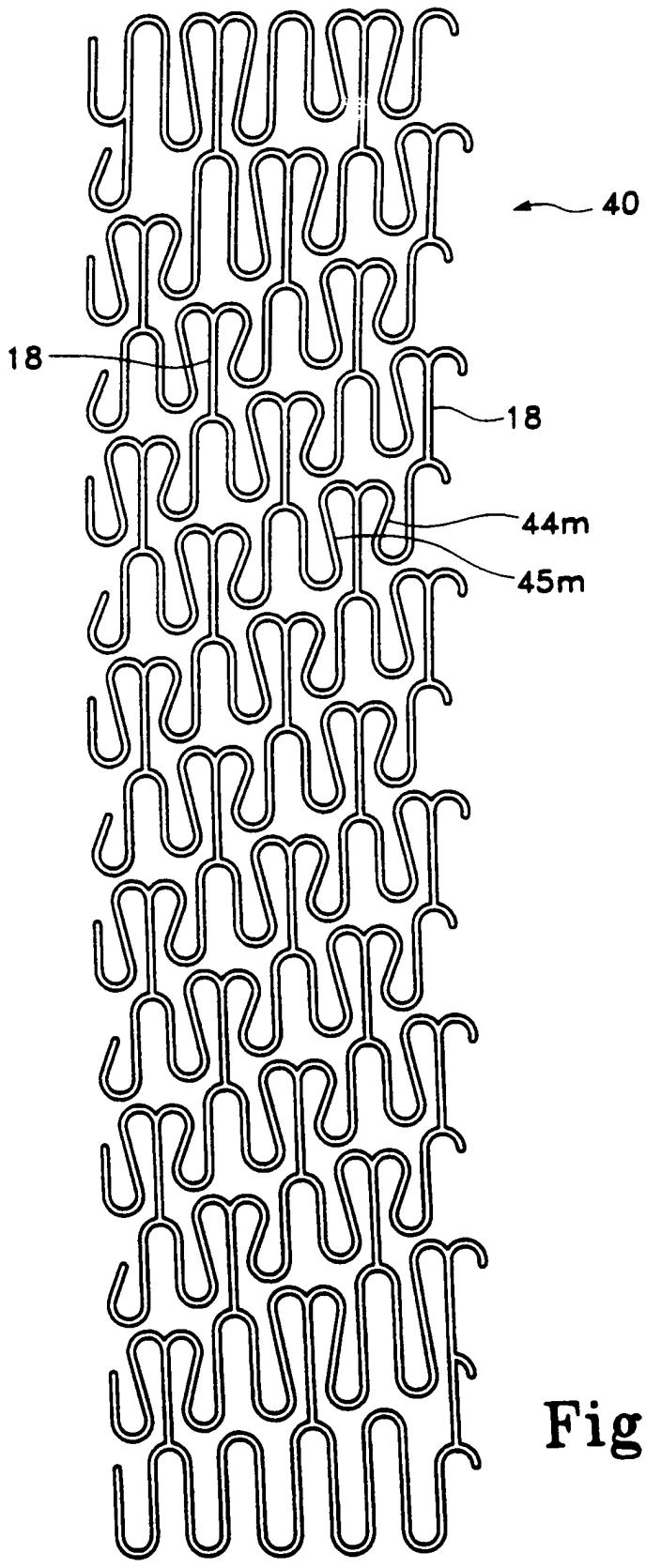


Fig. 9

Figure 14C is a cross-section view taken along section line 14C-14C depicted in Figure 14A.

Figure 14D is a cross-sectional view taken along section line 14D-14D depicted in Figure 14A showing an alternate embodiment.

Figure 15 is a front view of the assembled bifurcated stent-graft of Figure 14A placed at a bifurcation site within the vasculature of a body.

Figure 16 is a perspective break-away view showing a close-up of one construction of stent anchors according to the present invention.

Figure 17 is a perspective break-away view showing a close-up of a preferred construction of the stent anchors.

Figure 18 is a cross-sectional view of the stent-graft of Figure 14B taken along section line 18-18.

Figure 19 is a cross-sectional view of the stent-graft of Figure 14A taken along section line 19-19.

Figure 20 is an enlarged partial cross-sectional view of the contralateral leg connection depicted in Figure 19.

Figure 21 and Figure 22 are enlarged partial cross-sectional views of alternative constructions of the receiving lumen.

Figure 23 is a partial perspective view of an alternate scalloped construction of the proximal region of the contralateral leg component.

Figures 24A and 24B are cross-sectional views taken along section line 24A-24A as shown in Figure 14A depicting a free state and a forced state respectively.

Figures 25A and 25B are cross-sectional views taken along section line 25A-25A as shown in Figure 23 depicting a free state and a forced state respectively.

Figure 26 is a front view of graft components prior to assembly.

Figures 26B and 26C are respectively the front view and top view of the assembled graft of Figure 26A.

Figure 27A is a front view of the unassembled components of an alternate construction of the graft element.

Figure 27B is a front view of the assembled graft element according to the alternative construction of Figure 27A.

Figures 28A, 28B, 28C, 28D, and 28E diagrammatically show deployment of a bifurcated stent-graft.

Figures 29A, 29B and 29C diagrammatically show deployment of a bifurcated stent-graft using an alternate delivery system.

DETAILED DESCRIPTION

The following disclosure relating to the present invention will use certain nomenclature as set forth below. The term distal, as hereinafter used, is meant to refer to locations that are furthest away from the catheter delivery hub. Proximal is meant to refer to locations that are closer to the catheter delivery hub.

Referring to the drawings in detail wherein like numerals indicate like elements, the present invention generally involves bifurcated implants such as stents or stent-grafts for delivery to a desired site through a body's vasculature. This may involve delivery systems that can be used in conjunction with such implants. As this invention is a involves both bifurcated components as well as non-bifurcated components, it is worthwhile to begin by describing in detail the general prosthesis construction and and preferred manner of deployment that is applicable to both straight and bifurcated stents or stent-grafts in accordance with Figures 1-13. The bifurcated prosthesis will be described with relation to Figures 14-28.

Although the invention will be described with reference to the delivery examples illustrated in the drawings, it should be understood that it can be used in conjunction with other delivery devices having constructions different than those shown.

For illustrative purposes, this invention will be described with reference to the location in the human body where the abdominal aorta bifurcates into the left and right (or ipsalateral and contralateral) iliac arteries. It should be understood, however, that the present invention may be used at many other locations within the body.

Referring to Figures 1 through 13, delivery systems for delivering implants or devices, such as stents or stent-grafts, to a desired site in mammalian vasculature are shown. Such delivery systems generally include a restraining member that is adapted and configured for surrounding at least a portion of a collapsed or compressed implant

and a coupling member(s) for releasably coupling portions of the restraining member to one another to maintain the implant in its collapsed or compressed state.

Referring to Figures 1-4, an implant delivery system is shown. Delivery system (100), generally includes a restraining member (102), which as shown may be in the form of a sheet of material, and a coupling member (104) for releasably coupling portions of the restraining member to one another. The restraining member portions that are coupled may differ than those illustrated, but preferably are selected to maintain the implant, such as self-expanding stent-graft (106), in a collapsed or compressed state as shown in Figures 1 and 2 where the restraining member (102) is shown in the form of a tube. In the illustrative embodiment, the coupling member (104) is shown as a filament or thread-like element which prevents the restraining member (102) from rearranging to a configuration where the stent-graft (106) could expand to its expanded state.

The implant may be collapsed in any suitable manner for placement within the restraining member (102). For example, the implant may be folded or radially crushed before placement within the restraining member (102) as will be described in more detail below. As shown in Figures 9-11, a delivery assembly (108), which includes the restraining member (102) and the stent-graft (106), has relatively small cross-sectional dimensions which facilitate endolumenal delivery of the assembly to a site where the natural lumen diameter may be smaller than the expanded diameter of the stent-graft (106).

Referring to Figures 3 and 4A, the assembly (108) is shown in a deployed state after removal of the coupling member (104). The restraining member (102) may be fixedly secured to the stent-graft (106) so that the two components remain attached after expansion at the desired deployment site. The attachment between the restraining member and the implant preferably is made to prevent significant movement between the restraining member and stent-graft after deployment which could disrupt endovascular fluid flow. Referring to Figures 4A and 4B multiple sutures (110) may be used to fixedly attach the restraining member (102) to the stent-graft (106). More specifically, the sutures can form loops that pass through the restraining member and around portions of the stent as shown in Figure 4A. It is

further noted that although one arrangement of the sutures (110) is shown in Figure 4B other arrangements may be used.

Although other configurations of the restraining member (102) can be used, a preferred configuration is a generally rectangular one having constant width as shown in Figure 4B. For example, in the case where the restraining member is used in conjunction with a modular bifurcated stent as will be described below, the restraining member may have a similar rectangular configuration as that shown in Figure 4B. Alternatively, it may have two differently sized rectangular portions arranged to mate with the regions of different diameter (trunk and leg) or another configuration that would maintain the implant in a collapsed stent when secured. Returning to Figure 4B, the restraining member may be described as having side margins (112) that extend between the ends (114) of the member. Eyelets (116) are disposed along the side margins so that the coupling member (104) may be laced or threaded therethrough. The eyelets may be in the form of through holes (118), which may be formed by a uniform-diameter puncturing device or by other means such as laser-drilling. Alternatively, the eyelets may be formed by loops (120) which may be attached to the side margins (112) or formed by other means as would be apparent to one of ordinary skill in the art.

It is further desirable to have structural reinforcement at the side margins (112) to minimize or eliminate the possibility of the coupling member (104) from tearing the restraining member (102) when under load. Reinforced side margins may be formed by folding a portion of the restraining member (102) over a reinforcement member (122), such as a small diameter suture, which may be heat bonded between the two layers of sheet material. With this construction, a relatively low profile bead of material along the side margins (112) prevents or minimizes the possibility of tear propagation and, thus, accidental uncoupling of the restraining member (102). The small diameter suture (122) may comprise ePTFE, for example.

As the restraining member (102) constrains a collapsed self-expanding stent-graft, for example, forces resulting from stored spring energy in the collapsed stent-graft (106) will be acting on the restraining member (102) when it is configured for delivery. Thus, the restraining member (102) may comprise a material which is creep resistant and can withstand required loads without stretching over time. The

restraining member (102) may comprise, for example, ePTFE, which is believed to provide suitable creep resistance, flexibility, and biocompatibility in a thin sheet form which can be heat bonded. Other materials also may be used including polyethers such as polyethylene terepthalate (DACRON® or MYLAR®) or polyaramids such as KEVLAR®.

The thread-like coupling member (104) may also comprise ePTFE. Sutures of polyethers such as polyethylene terepthalate (DACRON® or MYLAR®) or polyaramids such as KEVLAR® or metal wire comprising nitinol, stainless steel or gold may also be used for the coupling member (104). The coupling member (104) may simply extend to form a remote pull line as will be discussed below. Alternatively, a metallic pull line, such as one comprising stainless steel may be coupled to a nonmetallic coupling member (104) such as one comprising ePTFE. The coupling may be made by folding the end of the metallic pull line back upon itself to form an eyelet and threading the coupling member therethrough and securing it to the eyelet with a knot.

It is further noted that the width of the restraining member, when in a flat orientation as shown in Figure 4A, preferably is less than the diameter of the implant. Typically the restraining member width will be less than about 40mm (typically about 25-40mm when the device is sized for thoracic aorta applications), and typically less than about 15mm in other applications where the lumen is smaller. The sheet of material preferably has a thickness less than .010 inch (0.254 mm) and more preferably less than .005 inch (0.127 mm). In addition, the length of the restraining member preferably is less than or equal to that of the implant.

Additionally, a retraction assembly may be provided to retract the restraining member during expansion of the implant, so that the length of the restraining member is maintained to be about equal to or less than that of the implant. The expandable portion of the implant may undergo minor amounts of shortening along the axial direction due to the expansion thereof in the radial direction, which may lead to an overlap of the restraining member at the ends of the implant, but for the use of some type of retraction assembly in these situations. The retraction assembly minimizes or eliminates the risk of the restraining member extending beyond the implant and

interfering with any channel formed by the implant, or any fluid flowing therethrough after expansion.

Referring to Figures 5A-5D, retraction assemblies or mechanisms are shown. In Figure 5A, a retraction assembly (340) is shown including a biocompatible filament (342), which includes a portion that is stitched, tied or otherwise fixed to the restraining member (102), as shown at an attachment point (348), adjacent to one end of the restraining member. Filament (342) is passed underneath the members forming the first or end helical turn of the stent (126) and looped under or otherwise slidably secured to a portion of the second , third or another helical turn other than the first helical turn such a an apex or bend portion (344) in a second turn. The other end portion of filament (342) is further fixed, by tying or other means, to a portion of the stent that is circumferentially spaced from the attachment point (348) or the apex or bend portion (344), for example, such as an apex or bend portion (346) of the same helical turn. Preferably, the filament (342) is looped through an apex portion (344) of the second helical turn and tied to an apex portion (346) which is adjacent to the apex portion (344) as shown in Figure 5A.

Figure 5A shows the stent in the compressed state. Upon expansion of the stent, as mentioned above, the members of the stent expand to effect the radial expansion of the stent, as shown in Figure 5B. Because the distance between apex portions (344) and (346) becomes greater upon expansion of the stent, and because the filament (342) is relatively unyieldable and inelastic, the distance between the attachment point (344) and the apex portion (348) necessarily decreases. The result is that the end of the restraining member (102) is retracted with respect to the stent (126), as shown in Figure 5B. Thus, the retraction along the longitudinal axis of the restraining member is driven by the expanding distance between adjacent apexes in this embodiment. Although only one retraction mechanism is shown at one end of the restraining member, another similarly configured and arranged retraction mechanism may be used at the other end of the restraining member.

Figures 5C and 5D show another embodiment for a retraction assembly. The views of this assembly (as are those shown in Figures 5A and 5B) are taken from a location between the generally cylindrical graft and stent looking radially outward. In contrast to that shown above where one end portion of a filament is secured to the

restraining member and another to a portion of the stent that circumferentially moves during stent expansion, the other end of the filament is secured to a portion of a stent that moves generally parallel to the longitudinal axis of the stent (axially) as the stent expands. In this embodiment, at least one apex portion (364) of an end helix of the stent member (126') (which differs from stent (126) in that it includes eyelets or loops which may be formed as shown in the drawings) is made shorter than the majority of apex portions (366). However, the apex portions may be otherwise configured such as those shown in Figures 4A and 4B. A filament (362) is tied or otherwise fixed at one end to apex portion (364), and at the other end, to one end portion of the restraining member (102). As shown in Figure 5D, upon radial expansion of the stent, inwardly positioned apex portion (364) retracts to a greater extent in the longitudinal or axial direction than the full height apex portions (366) which are shown in the last or most outwardly positioned turn of the stent. This relative greater retraction directly translates through filament (362) such that the end of the restraining member (102) is retracted relative to apex portions (366). As described above, another similarly constructed retraction mechanism may be provided at the other end of the restraining member.

Returning to Figure 1, one stent-graft construction that may be used in conjunction with the delivery systems disclosed herein is shown. Stent-graft (106) generally includes a thin-walled tube or graft member (124), a stent member (126), which can be a self-expanding stent, and a ribbon or tape member (128) for coupling the stent (126) and graft (124) members together. The stent (126) and graft (124) members may be heat bonded together, thus sealing in portions of the stent member (126) that are between the tape member (128) and the graft member (124). The mechanical properties of the stent-graft (128) may be customized, for example, through materials selection, by varying the structural pattern of the stent member, varying the thickness of the tape (128) and graft (124) members, and varying the pattern with which the tape member contacts the stent and graft members.

As shown in Figure 1A, the tape member (128) may cover only a portion of the stent member (126) as it follows the helical turns of the undulating stent member. With this construction, regions of the stent member do not interface with the tape member when the stent-graft is in an uncompressed state, for example. This is

believed to advantageously reduce shear stresses between the stent member (126) and the tape member (128) when the stent-graft undergoes bending or compression, thereby reducing the risk of tearing the graft (124) or tape (128) members or causing delamination between the stent (126) and graft (124) members.

The tape member (128) also preferably has a generally broad or flat surface for interfacing with the stent (126) and graft (124) members as compared to filament or thread-like structures such as sutures. This increases potential bonding surface area between the tape member (128) and the graft member (124) to enhance the structural integrity of the stent-graft. The increased bonding surface area also facilitates minimizing the thickness of the tape member (128). It has been found that a tape member in the form of a generally flat ribbon as shown in the drawings provides desired results.

Tape members having widths of 0.025, 0.050 and 0.075 inches applied to a stent member having a peak-to-peak undulation amplitude of about 0.075 inch are believed to provide suitable results. However, it has been found that as the tape member band width increases, the stent-graft flexibility generally is diminished. It is believed that a tape member width of about one-fourth to three-fourths the amplitude of the stent member undulations, measured peak-to-peak, may be preferred (may be more preferably about one-third to two-thirds that amplitude) to optimize flexibility. It also has been found that by positioning one of the lateral margins of the tape member adjacent to the apexes, the tape member width may be reduced without significantly sacrificing apex securement. Varying the width of the tape member (e.g., varying width of the tape along the length of the stent graft) can also result in the adjustment of other structural properties. Increasing the width can also potentially increase the radial stiffness and the burst pressure and decrease the porosity of the device. Increasing band width can also diminish graft member wrinkling between coupling member turns.

The tape member (or separate pieces thereof) also may surround the terminal end portions of the stent-graft to secure the terminal portions of the graft member to the stent member.

Figures 6A and 6B illustrate further stent-graft constructions that may be used with the delivery systems described herein. Referring to Figure 6A, stent-graft (200)

is the same as stent-graft (106) with the exception that stent-graft (200) includes a filament that couples stent undulations in adjacent turns. Filament (202) is laced or interwoven between undulations of the stent member and acquires a helical configuration (i.e., it forms a secondary helix) in being laced as such. Such a configuration is disclosed in PCT publication No. WO 95/26695 (International Application No. PCT/US95/04000) the entirety of which is hereby incorporated herein by reference. The stent-graft (300) shown in Figure 6B is the same as that shown in Figure 6A with the exception that the filament (302) is interwoven between undulations in the same helical turn of the stent member.

The filaments (202, 302) are of the same construction and may be of any appropriate filamentary material which is blood compatible or biocompatible and sufficiently flexible to allow the stent to flex and not deform the stent upon folding. Although the linkage may be a single or multiple strand wire (platinum, platinum/tungsten, gold, palladium, tantalum, stainless steel, etc.), much preferred is the use of polymeric biocompatible filaments. The flexible link may be tied-off at either end of the stent-graft (100), for example, by wrapping its end portion around the stent and tying it off at the point at the beginning of the last turn as would be apparent to one of ordinary skill.

A percutaneously delivered stent-graft must expand from a reduced diameter, necessary for delivery, to a larger deployed diameter. The diameters of these devices obviously vary with the size of the body lumen into which they are placed. For instance, the stents typically may range in size from 2.0mm in diameter (for neurological applications) to 40mm in diameter (for placement in the aorta). A range of about 2.0mm to 6.5mm (perhaps to 10.0mm) is believed to be desirable. Typically, expansion ratios of 2:1 or more are required. These stents are capable of expansion ratios of up to 5:1 for larger diameter stents. Typical expansion ratios, for instance, typically are in the range of about 2:1 to about 4:1. The thickness of the stent materials obviously varies with the size (or diameter) of the stent and the ultimate required yield strength of the folded stent. These values are further dependent upon the selected materials of construction. Wire used in these variations are typically of stronger alloys, e.g., nitinol and stronger spring stainless steels, and have diameters of about 0.002 inches to 0.005 inches. For the larger stents, the appropriate diameter for

the stent wire may be somewhat larger, e.g., 0.005 to 0.020 inches. For flat stock metallic stents, thicknesses of about 0.002 inches to 0.005 inches is usually sufficient. For the larger stents, the appropriate thickness for the stent flat stock may be somewhat thicker, e.g., 0.005 to 0.020 inches.

The following example is provided for purposes of illustrating a preferred method of manufacturing a stent-graft as shown in Figure 3. It should be noted, however, that this example is not intended to be limiting. The stent member wire is helically wound around a mandrel having pins positioned thereon so that the helical structure and undulations can be formed simultaneously. While still on the mandrel, the stent member is heated to about 460°F for about 20 minutes so that it retains its shape. Wire sizes and materials may vary widely depending on the application. The following is an example construction for a stent-graft designed to accommodate a 6mm diameter vessel lumen. The stent member comprises a nitinol wire (50.8 atomic % Ni) having a diameter of about 0.007 inch. In this example case, the wire is formed to have sinusoidal undulations, each having an amplitude measured peak-to-peak of about 0.100 inch and the helix is formed with a pitch of about 10 windings per inch. The inner diameter of the helix (when unconstrained) is about 6.8mm. (The filament when used as shown in Figures 6A and 6B may have a diameter of about 0.006 inch.)

In this example, the graft member is porous expanded polytetrafluorethylene (PTFE), while the tape member is expanded PTFE coated with FEP. The tape member is in the form of a flat ribbon (as shown in the illustrative embodiments) that is positioned around the stent and graft member as shown in Figure. 3. The side of the tape member or ribbon that is FEP coated faces the graft member to secure it to the graft member. The intermediate stent-graft construction is heated to allow the materials of the tape and graft member to merge and self-bind as will be described in more detail below.

The FEP-coated porous expanded PTFE film used to form the tape member preferably is made by a process which comprises the steps of:

(a) contacting a porous PTFE film with another layer which is preferably a film of FEP or alternatively of another thermoplastic polymer;

(b) heating the composition obtained in step (a) to a temperature above the melting point of the thermoplastic polymer;

(c) stretching the heated composition of step (b) while maintaining the temperature above the melting point of the thermoplastic polymer; and

(d) cooling the product of step (c).

In addition to FEP, other thermoplastic polymers including thermoplastic fluoropolymers may also be used to make this coated film. The adhesive coating on the porous expanded PTFE film may be either continuous (non-porous) or discontinuous (porous) depending primarily on the amount and rate of stretching, the temperature during stretching, and the thickness of the adhesive prior to stretching.

In constructing this example, the thin wall expanded PTFE graft was of about 0.1mm (0.004 in) thickness and had a density of about .5g/cc. The microstructure of the porous expanded PTFE contained fibrils of about 25 micron length. A 3cm length of this graft material was placed on a mandrel the same diameter as the inner diameter of the graft. The nitinol stent member having about a 3cm length was then carefully fitted over the center of the thin wall graft.

The stent-member was then provided with a tape coupling member comprised of the FEP coated film as described above. The tape member was helically wrapped around the exterior surface of the stent-member as shown in Figure 3. The tape member was oriented so that its FEP-coated side faced inward and contacted the exterior surface of the stent-member. This tape surface was exposed to the outward facing surface of the thin wall graft member exposed through the openings in the stent member. The uniaxially-oriented fibrils of the microstructure of the helically-wrapped ribbon were helically-oriented about the exterior stent surface.

The mandrel assembly was placed into an oven set at 315°C for a period of 15 minutes after which the film-wrapped mandrel was removed from the oven and allowed to cool. Following cooling to approximately ambient temperature, the mandrel was removed from the resultant stent-graft. The amount of heat applied was adequate to melt the FEP-coating on the porous expanded PTFE film and thereby cause the graft and coupling members to adhere to each other. Thus, the graft member was adhesively bonded to the inner surface of the helically-wrapped tape member through the openings between the adjacent wires of the stent member. The combined thickness of the luminal and exterior coverings (graft and tape members) and the stent member was about 0.4mm.

Although the delivery systems have been described with reference to the stent-graft examples illustrated in the drawings, it should be understood that it can be used in conjunction with other devices, stents or stent-grafts having constructions different than those shown. For example, delivery systems described herein may be used in conjunction with bifurcated stents or stent-grafts as will be described in detail below. In addition, although a self-expanding stent-graft has been described, balloon expanding stent-grafts also may be used in conjunction with the delivery systems described herein. These stent-grafts require a balloon to expand them into their expanded state as opposed to the spring energy stored in a collapsed self-expanding stent.

Referring to Figures 7A-C, one slip knot configuration that may be used in conjunction with the thread-like coupling member (104) will be described. The restraining member (102) is shown without an implant positioned therein for purposes of simplification. Figure 7A illustrates the slip knot in a prerelease or predeployment state. The series of knots are generally flush with the restraining member (102) surface and add very little profile to the construct which is preferred during implant delivery. Figure 7B shows the assembly of Figure 7A with the thread-like coupling member (104) loosened to illustrate how the chain knots (130) may be formed. Figure 7C diagrammatically represents release of the assembly of Figure 7A or 7B. The illustrated stitch is releasable by pulling one end of the line that results in releasing of the cylindrical or tubular restraining member and then deployment of the device. This particular stitch is called a chain stitch and may be created with a single needle and a single line. A chain stitch is a series of loops or slip knots that are looped through one another such that one slip knot prevents the next slip knot from releasing. When the line is pulled to release a slip knot, the following slip knot is then released and that releases the next slip knot . This process continues during pulling of the line until the entire line is pulled out of the restraining member.

Referring to Figures 7A-C, as the unknotted portion or the lead (132) of the thread-like coupling member (104) is pulled, such as in the direction shown by reference arrow (134), each consecutive chain knot (132) releases the next adjacent one. In the preferred embodiment, the chain knots (130) of the coupling member (104) are arranged to progressively release the collapsed implant in a direction away

from the distal portion of the delivery catheter as shown in Figure 10A and as will be discussed in detail below.

Referring to Figures 8A through 8F, a method for making an assembly comprising a restraining member with a collapsed or compressed implant therein is shown for purposes of example. Figure 8A shows the restraining member (102) with its side margins releasably coupled to one another and its left end dilated by a tapered mechanical dilator (402). A small funnel (404) is then inserted into the restraining member (102) as shown in Figures 8B and 8C. The small funnel (404) and restraining member (102) are then mounted onto a pulling frame (410), and a large funnel (406) is fitted into the small funnel (404) as shown in Figure 8D. Traction or pull lines (408), which have been sutured to one end of the stent-graft, (106) are pulled through the large funnel (406), small funnel (404), and restraining member (102) with a tapered mandrel (416). As shown in Figures 8F, the pull lines (408) are fastened to a tie down post (412) located on a tension screw (414) and then are pulled by the tension screw (414). The stent-graft (106) is then pulled and collapsed sequentially through the large (406) and small (404) funnels, and then into the restraining member (102). Once the stent-graft (106) has been radially collapsed into the restraining member (102), which has its side margins coupled together, the pull lines (408) can be removed. The mandrel (416) may be inserted into the restrained implant to facilitate introduction of another component. In the preferred embodiment, a multilumen catheter (136) (Figures 9-11) is introduced through the center of the compressed stent-graft (106) and is used to deliver the radially restrained stent-graft to the desired endolumenal site.

It also is noted that the funnels may be chilled to facilitate compression of the stent when the stent is made of nitinol. That is, when the stent is made of nitinol, the funnels may be chilled below 0°C or below the transition temperature (M*f*) where nitinol is in its martensitic state. In addition, the stent-graft could be folded first and then reduced in profile by pulling through the funnel and into the restraining member. Cooling may be accomplished by spray soaking the stent-graft with chilled gas such as tetrafluroethane. Micro-Dust ™ dry circuit duster manufactured by MicroCare Corporation (Conn) provides suitable results. The spray canister preferably is held upside down to discharge the fluid as a liquid onto the stent-graft.

A method of deploying an implant will be described with reference to Figures 9-11. In general, an implant may be delivered percutaneously with the delivery systems described herein, typically through the vasculature, after having been assembled in the reduced diameter form (see e.g. Figure 1). At the desired delivery site, the implant may be released from the restraining member, thus allowing the implant to expand or be expanded against the lumen wall at the delivery site. Although other devices including stents or stent-grafts may be used, such as balloon expandable stents, the following example will be made with reference to a self-expanding stent-graft, which has the ability to fully expand itself into its final predetermined geometry when unconstrained. More particularly, the following example will be made using a delivery system as shown in Figures 1 and 7A-C and a stent-graft construction as shown in Figure 3.

Referring to Figures 9A and 9B, an implant delivery assembly including a collapsed stent-graft (106) that is confined within a restraining member (102) and, which surrounds a distal portion of the delivery catheter (136), is shown. The attending physician will select a device having an appropriate size. Typically, the stent-graft will be selected to have an expanded diameter of up to about 20% greater than the diameter of the lumen at the desired deployment site.

The delivery catheter preferably is a multilumen catheter. The proximal portion of the catheter (136) is coupled to a hub (140), which includes a guidewire port (142) for a guidewire (142), and a deployment knob (144), which is coupled to the lead (132) of the thread-like coupling member (104). Accordingly, when the knob (144) is retracted, the restraining member (102) is released so that the stent-graft may expand. The hub (140) also may include a flushing port (146) as is conventional in the art. The stent-graft (106) is held axially in place prior to deployment by a proximal barrier (148) and distal barrier (150) which are positioned around delivery catheter (136) adjacent to the proximal and distal portions, respectively, of the restrained stent-graft. The proximal and distal barriers (148, 150) may be fixedly secured to the multilumen catheter (136) to restrict any axial movement of the restrained stent-graft. The barriers preferably are positioned to abut against the stent-graft or restraining member. The lead (132) of the coupling member (104) is passed through an aperture (152) in the proximal barrier (148) which is fluidly coupled to a

lumen in the delivery catheter (136) so that the coupling member lead (132) can be coupled to the deployment knob (144). Figures 9A and 9B show advancement of the catheter (136) and the restrained implant through a vessel (154) toward a desired site. Referring to Figures 10A and 10B, once the restrained stent-graft reaches the desired site (156), the deployment knob (144) is retracted so that the stent-graft progressively expands as shown in the drawings as the coupling member (104) is removed from the restraining member. The coupling member preferably is arranged to facilitate stent-graft expansion in a direction from the distal to proximal ends of the stent-graft (i.e., in a direction from the catheter tip to the catheter hub). Figures 11A and 11B show the stent-graft (106) and restraining member (102) in their final implantation position after the coupling member and catheter have been removed therefrom. In another embodiment, multiple restraining members may be used as shown in Figure 9C. When the multiple coupling members (104) are released simultaneously implant deployment time may be reduced.

A method for deploying a balloon expandable stent-graft may be the same as that described above, with the exception that after the coupling member (104) has been retracted from the eyelets (116), the balloon, which may be positioned inside the stent-graft prior to delivery, is inflated to expand the stent-graft (106) and then deflated for removal through the catheter (136).

According to further embodiments, multidirectional coupling member release or multiple coupling members may be used. These configurations may facilitate more rapid deployment of the implant than when a single unidirectional coupling member is used. Figures 12A - 12D diagrammatically show multidirectional deployment of a restrained implant where a coupling member arrangement is provided to release the implant from its middle portion, preferably its axial center, outward toward the implant ends. Although a particular coupling member configuration is not shown in these diagrammatic representations, one suitable coupling configuration is shown in Figure 13 where the leads (132) may be passed through the aperture (152) and coupled to the deployment knob (144) as shown in Figure 9A and described above.

Referring to Figure 12A, the restrained stent-graft, which is positioned on the distal end portion of delivery catheter (136), is advanced through a vessel (154) for deployment in an aneurysm (158). The axial midpoint of the restraining member

(102) preferably is positioned at the center of the aneurysmal sac. As the coupling member arrangement unlacing propagates from middle of the construct toward the proximal and distal ends of the restraining member (102) and the stent-graft (106), the stent-graft (106) progressively expands from its axial midportion toward its ends as shown in Figures 12B and 12C. This may be accomplished by pulling the leads (132) shown in Figure 13 simultaneously when the arrangement in that figure is used. The stent-graft size is selected so that when the restraining member is fully released and the stent-graft fully deployed as shown in Figure 12D, the proximal and distal portions of the stent-graft are positioned against the proximal and distal necks of the aneurysm. The delivery catheter may then be retracted.

As is apparent from the drawings, this embodiment advantageously allows fluid flow through the aneurysmal sac to remain substantially unobstructed during the release of the restraining member. For example, the stent-graft ends are still constrained at the deployment time shown in Figure 12C where the aneurysm neck regions are shown minimally obstructed. In addition, this simultaneous, multidirectional release of the restraining member advantageously reduces the time in which fluid flow in the vessel may disturb the implant position as it is deployed as compared to a single directional release mechanism such as that shown in Figures 9-11.

Referring to Figure 13, a multiple coupling member configuration is shown. The illustrated arrangement includes two lacing configurations (150) and (152). Except for the placement of the lead (132) of thread-like coupling member (104), configuration (152) is the mirror image of configuration (150). Accordingly, description of only one of the configurations will be made for purposes of simplification. Referring to the lacing configuration (152), configuration (152) is the same as that shown in Figures 7A-C with the exception that configuration (152) further includes two additional slip knots, generally designated with reference numeral (504), and tuck or loop arrangement (506). The additional slip knots are not interwoven in the restraining member and provide a delay mechanism for release of the coupling member, as is apparent from the drawings, when the lead (132) is pulled in the direction of the arrow (134). Thus, inadvertent pulling of the lead (132) will not immediately begin to release the coupling member from the restraining member. The

tuck arrangement simply involves tucking the slack from lead (132) under stitches at various intervals as shown so that the additional slip knots (504) may be pulled out of the way for delivery. In addition, the tuck or loop arrangement (506) provides an additional delay mechanism for release of the slip knots.

Bifurcated Stent or Stent-Graft.

The following describes a modular bifurcated stent-graft constructed for treating a bifurcation site within a mammalian body. The stent-graft components generally comprise a flexible graft member attached to a wire stent member using a tape member according to the principles discussed at length above. Preferably the stent-graft components are designed for compressed delivery and are self-expanding, in the manner described above.

The modular stent-graft of Figures 14A through 14D generally has two principal components; a main body (700) and a contralateral leg (730) each generally having a graft member attached to a stent member according to the description above. The main body (700) generally has a number of sections which have distinct overall constructions. A distal trunk section (708) has a single lumen structure beginning at a distal end (702) of the main body (700) and continuing until a bifurcation point (728). The bifurcation point (728) is the location within the prosthesis where the single lumen of the distal trunk section (708) bifurcates into internal two flow lumen.

An intermediate section (710) begins at the bifurcation point (728) and continues to the receiving hole (704). In the intermediate section (710), the stent-graft has an internal graft structure which is bifurcated into two lumen surrounded by a generally tubular, single-lumen stent structure. Finally, a proximal section (712) is a single lumen structure for both the stent member and the graft member and includes an ipsalateral leg (726) which terminates at an ipsalateral leg hole (706).

The graft member of the intermediate section (710) bifurcates the single lumen distal trunk section (708) into the ipsalateral leg (726) and an internal female receiving lumen (703). The receiving lumen (703) terminates at a receiving hole (704). The receiving hole (704) and receiving lumen (703) accommodate delivery and attachment of the contralateral leg component (730). Preferrably, the graft material at

the distal end (734) of the contralateral leg component (730) is scalloped as shown more clearly in Figure 23 discussed below.

The receiving hole (704) is supported by a wire structure around a substantial portion of its periphery so that the receiving hole (704) is held open after deployment. In a preferred embodiment the wire structure that supports the receiving hole (704) is an independent wire ring (714).

The independent wire ring (714) is located in the general area of the receiving hole (704) in the intermediate section (710). The independent wire ring (714) ensures that the graft material at the receiving hole (704) is supported in an open position to receive the distal end (734) of the contralateral leg (730). In absence of such support, the receiving hole (704) may not reliably open after delivery of the main body component (700) because within the intermediate section (710) the bifurcated graft member in the area of the receiving lumen (703) does not have full stent support on its interior periphery. This may be better seen in Figure 18 which shows the absence of any internal stent support of the interior graft periphery (785) in the area of the receiving lumen (703).

The independent wire ring (714) may be comprised of the same materials as the other stent-graft sections discussed above and is preferrably self-expanding. In a preferred embodiment, the independent wire ring comprises a single turn of an undulating wire stent material surrounded by at least one layer of tape which is heat bonded to the receiving hole (704). Alternatively, the independent wire ring (714) could be formed as the last turn of the main body (700).

A radiopaque marker may be used to make the receiving hole (704) visible during implantation. Such a marker may include a radiopaque wire adjacent to the independent wire ring (714). Such markers make it easier to see the location of the receiving hole (704) after deployment of the main body (700) within the mammalian body.

This construction of the intermediate stent section (710) as seen in cross-section in Figure 14C is characterized by a single-lumen stent member and bifurcated graft member and offers both a smaller compressed profile as well as simplified manufacturing over constructions which have discreet stented leg features. The compressed profile is determined largely by the physical amount of stent and graft

material present in a given section. This construction eliminates the stent material that would normally support the inside periphery of the bifurcated graft section resulting in less stent material to compress in that region. As the main body component (700) is compressed for delivery as discussed above, the compressed profile is significantly smaller than would be a structure that had a section of bifurcated stent over the section of bifurcated graft.

Even though bifurcated flow is supported, manufacturing is simplified because there is no bifurcated stent section. Winding a bifurcated stent section in one piece, for example, is a more complex process. Likewise, winding separate cylindrical stent structures and connecting them to form a bifurcated stent structure is complicated and ultimately may be less reliable. The intermediate section (710) allows the entire stent member that covers the main body component (700) to be made from a single undulating wire arranged in multiple helical turns. The result is a bifurcated stent-graft device which is simple to manufacture, easily compressible and which expands reliably upon deployment.

An alternate construction of the intermediate stent section (710), is shown in Figure 14D. The intermediate stent section (710') has a shape characterized by the indented regions (727). The shape could generally be described as a 'figure-8', except that the area between the bifurcated graft member remains unsupported at its centermost region. This construction is still a single lumen stent construction and therefore maintains much of the benefits of reduced profile and simplified manufacturability while providing the bifurcated graft member with increased support around a greater portion of its perimeter. Further, indented portions (727) have less of a tendency to spring outward upon application of external forces.

As mentioned above, the main body component (700) and the contralateral leg component (730) are adapted for delivery in a compressed state to a bifurcation site within a body. For this purpose the main body component (700) is preferably equipped with a restraining member (722) constructed as described above. Likewise, the contralateral leg component (730) has an attached restraining member (732). These restraining members are typically sutured to the graft material at intervals down their length.

Figure 15 shows an assembled bifurcated stent-graft (740) after deployment at a bifurcation site within a bifurcated body vessel afflicted with an aneurysm (758). Although not intended to be so limited to any particular location, the inventive prosthesis is shown at the location where the abdominal aortic artery (752) bifurcates into the left iliac artery (756) and the right iliac artery (754). So that the various features of the inventive implant are more clearly shown, the restraining member is not shown in Figure 15.

The assembled bifurcated stent-graft (740) is comprised of the main body component (700) and the contralateral leg component (730). The distal end (734) of the contralateral leg component (730) has been inserted into the receiving leg hole (704) and the female receiving lumen (703) of the main body component (700).

For best results in deploying any stent or stent-graft of these types it is essential that they have the appropriate structural properties such as axial stiffness, flexibility and kink-resistance. With complicated structures, such as those required for treating a bifurcated site, it is increasingly difficult to obtain the desired structural properties because optimizing one may negatively effect the other.

For instance, optimizing the global axial stiffness of a stent or stent-graft will necessarily make the device significantly less flexible and consequently impair its resistance to kinking and lessen its ability to conform to the natural bends of curves the body's vasculature. Conversely a device that has high flexibility with little axial stiffness is difficult to properly deploy and does not aid in anchoring the device in the desired location.

With these constraints in mind, it has been discovered that having a bifurcated stent-graft which has segments constructed with varying structural properties offers improved deployability, is less susceptible to kinking, and favorably tends to maintain its desired position after deployment while allowing sufficient flexibility to accommodate movement by the body. The exact structural properties desired may depend on the location where the prosthesis is to be deployed.

For these reasons, it is preferable that the bifurcated stent or stent-graft be constructed with at least two segments having structural properties different from one another. For example, in Figure 14A, a length of the distal section (708) and the intermediate section (710) may be constructed with a higher axial stiffness for

improved deployment and positional stability while the proximal section (712) may be constructed to have higher flexibility to accommodate the geometry of the iliac artery.

It may be further desirable to have a number of segments that have different structural properties. Accordingly, the main body component (700) and the contralateral leg component (730) of the assembled stent-graft (740) have segments constructed with structural properties different from adjacent segments. In one preferred embodiment shown in Figure 15, the main body component (700) has four different segments constructed with different structural properties. The distal segment (742) is constructed to have higher axial stiffness than the more flexible proximally adjacent segment (744). The proximal section (748) is constructed to have a higher flexibility than that of its distally adjacent segment (746). Likewise the contralateral leg component (730) has an axially stiffer distal segment (750) and a more flexible proximal segment (749).

There are a number of ways to alter the structural properties of stent or stent-graft components. One way of selectively altering the structural properties of a stent-graft segment is to use a tape member for that segment that has different physical dimensions. Such a tape member is discussed above with reference to the tape member (128) of Figure 1. For example the tape member width, thickness or spacing may be increased, from the preferred dimensions discussed above, in a segment where it is desirable to have increased or decreased stiffness. For example, the use of wider tape wound with closer spacing will increase the stiffness in that area.

Another way of selectively altering the structural properties of a stent or stent-graft segment is shown in Figures 14A and 15. Extended struts (718) and (719) may be used to increase the axial stiffness of a stent-graft segment. Extended struts are formed by extending an apex on one turn of the undulating wire until it contacts an apex on an adjacent turn. This contact between an extended strut and the apex of an adjacent stent turn provides an added amount of axial stiffness. In a preferred embodiment, a layer of tape (not shown) is applied around the device in a helical pattern that covers each of the apexes of the extended struts. This additional layer of taping keeps the strut pairs together.

Referring to Figure 14A, a first helical stent turn (720) and a second helical stent turn (721) have a generally undulating shape having apexes. An extended strut

(718) of the stent turn (720) is formed having its apex near or in contact with the apex of the stent turn (721) directly below. The extended strut (719) is similarly formed by extending an apex of the stent turn (721) directly down to contact the apex in the turn below. This pattern in continued, each time spacing the extended strut over one undulation. This results in a helical pattern of extended struts down the length of the device. Of course, the extended struts may be arranged in patterns other than the helical configuration described.

A number of these patterns may be employed in any one segment or the extended strut pattern may be used in other segments to increase axial stiffness. Preferably the distally adjacent segment (746) on the main body component (700) and the axially stiff distal segment (750) on the contralateral leg component are constructed with extended struts as shown.

Another important aspect of the present invention is achieving a secure position against the walls of the vessel lumen so that the deployed position is maintained and so that there is no leakage of luminal flow. Referring now to Figure 15, the distal end (702) is sized to properly fit the inside diameter of the target artery, in this case the abdominal aortic artery. Typically the prosthesis is designed to have an unconstrained diameter slightly larger than the inside of the target vessel.

The ipsalateral and contralateral legs of the assembled bifurcated stent-graft (740) are typically the same size at their distal ends (around 13 mm for example) regardless of the size of the distal end (702) and undergo tapered sections (724) and (738) that taper to a diameter which corresponds approximately to the internal diameter of the iliac arteries. These tapered sections (724) and (738) are preferable to abrupt changes in diameter as they tend to produce superior flow dynamics.

After deployment, the assembled bifurcated stent-graft (740) must establish sufficient contact with the healthy vessel lumen an each side of the aneurysm (758) so that the device does not migrate or dislodge when subjected to the relatively high fluid pressures and flow rates encountered in such a major artery, especially when the body again becomes mobile after recovery. Further, sufficient contact must be made so that there is no leakage at the distal end (702), the ipsalateral leg hole (706) or the proximal end (736) of the contralateral leg.

Anchoring or staying features that allow the stent or stent-graft exterior to anchor itself to the vessel lumen wall may be provided to help the device seal to the vessel wall and maintain its deployed position. For example, anchors (716) as seen in Figures 14A and 15 are provided on the main body component (700) and could also be provided on the contralateral leg component (730). Preferably the top stent portion (717) is directed angularly outward. This flared stent portion works to force the anchors (716) into the vessel wall as the top stent portion (717) expands under force into radial interference with the vessel wall upon deployment.

A preferred construction for an anchor (716) is shown in Figure 17. This construction involves extending two wires from the upper stent turn (762) under an apex of an adjacent lower stent turn (764). The two ends of stent wires (760 and 761) are then bent out and away from the graft material (768). Extended struts (771) are formed adjacent to each anchor in the manner described above except the extended struts extend under the adjacent lower stent turn (764) down to a third stent turn (765). This extended strut arrangement provides support for the anchors (716) and provides for low stresses in the wires (760 and 761) under the application of bending forces encountered as the prosthesis expands into the vessel wall. The extended struts (771) minimize the localized deformation of the stent-graft structure in the area of the anchors by providing broader support.

Another construction of the anchors (716') are shown in Figure 16. An anchor (716') is formed in the same manner except the ends of the anchor remain connected in a 'U-shape' configuration as shown. An anchor (716') may be formed at any location on the stent-graft. Most preferably, the anchors are formed in an evenly spaced pattern around the top stent portion (717) (Figure 14A).

It should be apparent that the anchors as described above are not limited in use to the stent-graft combination shown in the figures but indeed could be used in any non-bifurcated or stent only construction that require similar functionality.

Sealing at the vessel wall may also be enhanced by the alternate construction shown in Figure 17 by way of a sealing mechanism. A sealing mechanism can be used with any type of implant, including any of the implants discussed above. For purposes of illustration, the sealing mechanism is shown with reference to the bifurcated implant of Figure 14 and comprises seal member (772) as seen in detail in

Figures 16 and 17. The sealing mechanism described below can be used with any of the implants discussed above.

One preferred construction for seal member (772) in the variations shown in Figures 16 and 17 may be similar to the preferred construction for the tape member used in constructing the stent-graft tubular member, as is provided in reference to Figure 1A and Figure 3 above.

In general, a thin walled ePTFE tape is used for seal member (722) similarly as that for tape member (128), shown variously in the previous figures. The tape used for seal member (722) is adhered to the outer surface of the stent-graft, including over tape member (128), described previously for bonding the stent and graft members. Seal member (722) has an inner surface constructed of a similar material for either the outer surface of the tape member (128) or the outer surface of the graft-member (124), depending upon which surface the seal member is desirably adhered.

First cuff end (767) is bonded to the stent-graft outer surface and second cuff end (769) is not, in order to form the unadhered flange to function as a one-way valve against peri-stent-graft flow. Seal member (722) may be selectively adhered along its length in this manner by providing a variable inner surface to the seal member such that, upon heating, only the surface in the region of first cuff end (767) bonds to the outer surface of the stent-graft. For example, the inner surface of seal member (722) may have an FEP liner in the region of first cuff end (767) but not in the region of second cuff end (769). In this case, upon contacting an outer surface of the stent-graft that has a uniform FEP outer surface, only first cuff end (767) may be heat secured thereon.

Alternatively, seal member (722) may have a uniform inner surface, such as constructed of FEP, and a variable outer surface, such as with a selective portion of FEP, may be provided either on the tape member (128) or on the graft member (124) in the region where the heat bonding of seal member (722) is desired. Still further, seal member (722) may have a uniform surface and may be positioned over tape member (128) and graft member (124) so that variability between the outer surfaces of tape member (128) and graft member (124) causes a selective bonding with the first cuff end (767) over one of those surfaces.

Further to the construction of seal member (722), the particular wall thickness of the tape which may be used for this component should desirably be as thin as possible to functionally provide the flange-one-way-valve function for that member. This is because, since seal member (722) is over the outer surface of the other stent and graft components of the stent-graft, seal member (722) is believed to be the profile-limiting feature of the overall assembly. Therefore, in a particular design, seal member (722) may desirably be a thinner wall than for the tape member used to construct the stent-graft described in reference to Figures 1 and 3.

Further referring to the particular constructions and related methods just described for adhering seal member (722) to the outer surface of the underlying stent-graft, it should be apparent to one of ordinary skill in the art that the desired construction and heat securing technique for seal member (722) is premised upon the theory that, where one polymer meets a like polymer (such as FEP meeting FEP), heating under proper conditions will allow for a selected heat bond. The present invention, however, should not be construed as limited to these particularly described conditions, but instead should be considered to more broadly encompass any suitable means for securing a seal member to the outer surface of a given tubular member, as would be apparent to one of ordinary skill, and as is provided previously with reference to Figure 1.

Further there is a plurality of circumferential strut spaces between the struts of the stent member. It is believed that these spaces may provide a path for leakage flow around the outer surface of the graft member and along the outside of the stent-graft. Second cuff end (769), however, captures such leakage flow beneath its flange, which can not propagate along the outer surface of the stent-graft because first cuff end (767) is secured to the outer surface of that stent-graft. In other words, flow over the stent-graft and into an aneurysm is occluded.

Furthermore, when apex strut (716) is anchored into the wall of abdominal aortic artery as shown in Figure 15, it has been observed that the portion of main body component (700) at and adjacent to the apex strut (716) may be forced away from the artery wall. This action causes a separation between the outer surface of main body (700) and the artery wall, which separation is believed to create a leakage flow path.

The flange of seal member (772) captures that flow and occludes it from propagating into the aneurysm (758).

In addition to maintaining a good contact with the vessel lumen walls, the components of the stent-graft must make sufficient contact with each other such that the separate modules stay attached and do not leak at their engagement interface. The inventive stent-graft shown in Figure 18 illustrates several important features designed to effectuate a leak-free and positionally stable seal at the interface between the receiving lumen (703) of the main body component (700) and contralateral leg component (730).

Figure 18 shows a partial cross-section of the assembled stent-graft. The contralateral leg component (730) has been inserted into the receiving lumen (703) of the main body component (700). This cross-sectional view shows clearly that the main body component (700) includes a main body graft member (780) and a main body stent member (782). The contralateral leg component (730) includes a contralateral graft member (784) and a contralateral stent member (786).

At the interface between the contralateral leg component (730) and the receiving lumen (703), the assembly provides for an extending sealing region (790). Preferably the extended sealing region (790) consists of a generally cylindrical interfering friction fit between the outside diameter of the contralateral leg component (730) and the inside diameter of the receiving lumen (703). That is, the natural or resting outside diameter of the self expanding contralateral leg component (730) would be larger than the natural inside diameter of the receiving lumen (703). Thus the forces created by the interference act to seal the two components and also serve to resist movement of the two components.

The type of generally cylindrical extended sealing region just described has many advantages. First, it allows for the stent and graft structures in the extended sealing region (790) to be constructed of relatively simple generally cylindrical elements that are easily manufactured. Because the extended sealing region (790) extends over a large length it necessarily has a large surface area to effectuate sealing between the components. This larger sealing area typically provides that multiple turns of the stent structures will be engaged in an interfering and thus sealing relationship.

In one preferred embodiment, the extended sealing region has a length in excess of one-half of the diameter of the receiving lumen (703), more preferably the length is greater that the diameter of the receiving lumen (703), and most preferably the length is more than 2 times the diameter of the receiving lumen (703).

Because the manufacturing tolerances of the simplified shapes are easily controlled and because the engagement of the extended sealing region (790) is quite large, a highly reliable joint is formed between the modular components. Even so it may be desirable to create one or more localized zones of increased interference to increase the sealing capability and positional stability.

Localized zones of interference may be created in a number of ways. In a preferred embodiment, an annular ring of decreased diameter is formed within the receiving lumen. Such a localized decreased diameter causes a greater interference with the outside diameter of the contralateral leg component in a localized area while the remainder of the engagement with the receiving lumen is subject to the general interference friction fit described above.

One way of creating a localized decreased diameter is illustrated in Figure 20 which shows a partial cross-section of the extended sealing region (790). A zone of reduced diameter (799) is created by placing an anchoring ring (798) between the graft member (780) and the stent member (782) of the receiving lumen (703). The anchoring ring may be made from any polymeric or wire material, preferably a material that will not inhibit the receiving lumen from self-expanding to an open position. Most preferably the material is a suture material, typically ePTFE.

Alternately, localized zones of decreased diameter may be created as shown in Figures 21 and 22 by folding a portion of the graft member (780) back up into the receiving lumen (703). In Figure 21, the zone of reduced diameter (806) is formed by creating a folded flap (808) of the graft material (780) around an anchoring ring (802). The flap is heat bonded in place roughly at a location (804) as shown. In Figure 22, the zone of reduced diameter (809) is formed of flap (808) and heat bonded roughly at a location (807) in a similar manner but without any anchoring ring. The localized interference using these methods tends to cover a larger area and the flap (808) provides a more flexible member to seal against the outside diameter of the contralateral leg component (730).

One further aspect of ensuring a good seal between the stent-graft components involves the use of a scalloped stent-graft construction at the distal end of the contralateral leg component (810). To create this scalloped construction, the graft material between the apexes of the stent member is removed on the last turn of the stent. For example scallop (812) may be formed by removing (or cutting and folding under) the graft material from between a first apex (814) and an adjacent apex (816).

The advantage of using a scalloped arrangement are illustrated in Figures 24A through 25B. Figure 24A shows a cross-section of the fully expanded contralateral leg component (730) having an unscalloped construction. A first apex (822) and an adjacent apex (824) have continuous graft material (784) in the area between them. When the apex (822) and the adjacent apex (824) are forced together in the directions of the arrows (820), the graft material (784) forms a buckle or wrinkle (818) which is a potential leak path or is a potential site for thrombogenic material to build up as seen in Figure 24B. The scalloped construction shown in Figures 25A and 25B, on the other hand, have no graft material between the first apex (814) and the adjacent apex (816) and therefore when forced together do not form a graft material wrinkle.

The wrinkle (818), mentioned above may also be formed when the stent-graft is not allowed to expand to its complete diameter. For instance it is quite common that the receiving lumen or vessel wall internal diameter is smaller than the fully expanded stent-graft outer diameter. This being the case, it should be clear that the scalloped construction may alternately be used at any of the terminal openings of the main body component or the contralateral leg component. Preferrably, the distal end (702) of the main body component (700) also has this scalloped construction as shown in Figures 14A and !4B.

In the previous discussion we have referred generally to a stent-graft that includes a graft member. While the construction of such straight stent grafts are discussed at length above, the construction of a bifurcated graft member is illustrated in Figures 26, 27A and 27B. A bifurcated graft member suitable for construction of the main body component (700) discussed above is generally formed of two graft members: the ipsalateral tapered graft (840) and the contralateral tapered graft (842). The separate contralateral leg graft component (844) is a straight or tapered section and may be formed according to the principles discussed in the first section above.

The ipsalateral tapered graft (840) has three sections which are separated by tapers. A top section (846), a middle section (848), and a bottom section (850). The body component graft (854) is formed by heat bonding the top section (846) of ipsalateral tapered graft (840) to the top section (847) of contralateral tapered graft (842). This heat bonding forms a common septum (856) which in a preferred embodiment is subsequently cut away to produce a smooth bifurcation (858). Cutting away the septum material prevents fluid flow disturbance or blockage that could result from deviation of the septum. Such deviation is caused by the fluid pressure and is aggravated if the stent-graft is radially compressed in a manner which causes the septum to become loose or no longer taut.

In another embodiment, a graft section may be constructed in the manner illustrated in Figures 27A and 27B. According to this embodiment, the body component graft (867) is constructed from two pieces. A tubular graft section (860) is bent into a 'U-shape'. A top hole (864) is formed by notching the top of the 'U-shape'. Upper graft section (862) is placed over the top hole (864) of tubular graft section (860). The two pieces are bonded together at the bonding interface (866). Preferably, the two graft pieces are heat bonded while supported by interior mandrels (not shown) to obtain the desired shape and smooth interior. However, upper graft section (862) may be attached to the tubular graft section (860) at the bond interface (866) in any manner that provides a sufficiently leak free seal. For example the components may be sutured together or adhesive bonded.

In use, the modular bifurcated stent-graft is typically delivered percutaneously through the vasculature of the body. Preferably the prosthesis is delivered by way of a restraining member as described in detail above. Figures 28A though 28E diagrammatically illustrate deployment of a bifurcated stent-graft with a restraining member (902) using a percutaneous catheter assembly. Referring to Figure 28A, a multilumen catheter assembly (928) has been inserted to a selected site within a body lumen. The main body component (700) of a bifurcated stent-graft is held in a compressed state about a guidewire (926) and a guidewire lumen (929) by a restraining member (902) and a coupling member (906). The collapsed main body component (700) is held axially in place prior to deployment by a distal barrier (930) and a proximal barrier (932). The distal (930) and proximal (932) barriers are

typically affixed to the guidewire lumen (929). The coupling member (906) extends through the eyelets (920) of the restraining member (902) forming chain knots and into the multilumen catheter (928).

Figure 28A shows advancement of the multilumen catheter (928) with the distally located main body component (700) and the restraining member (902) into implantation position, typically at the bifurcation of a major vessel. During deployment it is critical that the surgeon align the main body component (700) so that the ipsalateral leg (726) will extend down one branch of the bifurcated vessel, and so the receiving hole (704) and the receiving lumen (703) will be lined up with the other branch of the bifurcated vessel so as to receive the contralateral leg component (730).

One way of facilitating this alignment is to provide radiopaque markers so that the surgeon may readily determine the rotational position of the main body component (700) prior to deployment or release from the restraining member (902). In a preferred embodiment, a long marker (934) is located on the contralateral side of the compressed assembly and a shorter marker (936) is placed on the ipsalateral side. Preferably these markers are placed on the stent prior to compression but may alternatively be part of the restraining member. Having one marker of a different length allows the surgeon to identify the orientation of both the ipsalateral leg and the receiving lumen relative to the bifurcated vessel.

Once the assembly is properly aligned and positioned for implantation, the coupling member (906) is pulled and the restraining member (902) begins to release the implant, typically at the distal end first. In the preferred embodiment, the restraining member (902) is located down the side as shown because it is less likely to interfere with deployment of the receiving lumen (703).

Figure 28B shows the main body component (700) radially expanding as the coupling member (906) is retracted through the eyelets (920) of the restraining member (902) and into the catheter assembly (928). In the preferred embodiment, the restraining member (902) has been fixedly attached to the main body component (700) with a number of sutures along the length of the main body component to prevent any relative longitudinal movement between the implanted prosthesis and the restraining member (902). The restraining member may optionally employ a retracting or pull-down mechanism as described at length above.

Figure 28C shows the main body component (700) and the restraining member (902) in final implantation position at the vessel bifurcation after the guidewire (926) and the catheter assembly (928) have been retracted.

Figure 28D shows the contralateral leg component (730) being delivered to the contralateral receiving hole using a restraining member (942). The procedure for positioning and releasing the contralateral leg component (730) is the same as that described above for implantation of a generally cylindrical stent-graft except that certain radiopaque markers may be employed to ensure its proper position relative to the bifurcation point (728) of main body component (700).

Radiopaque markers may be located, for example, to indicate the position of the receiving hole (704), the distal end (734) of the contralateral leg component (730), and the bifurcation point (728) of the main body component (700). These markers serve to indicate the position of the contralateral leg component as it enters the receiving hole (704) and its ultimate position relative to the receiving lumen (703) which begins at bifurcation point (728). In a preferred embodiment illustrated in Figure 19, the radiopaque wires (794) may be heat bonded or imbedded into the graft material (780) around the periphery of the receiving lumen. Such radioopaque wires could be used in other places such as the contralateral leg component lumen, the ipsalateral leg lumen or the lumen at the distal end of the main body component (700).

Figure 28E shows the assembled bifurcated stent-graft in its final implantation state with the contralateral leg component expanded into and engaged with the receiving lumen of the main body component (700).

Figures 29A through 29D diagrammatically show the same stent or stent-graft components being deployed except that the restraining member (902) is released from the center out towards as the coupling member (906) is retracted. This may provide more accurate placement relative to the bifurcation point of the vessel instead of relative to the distal end as with end release.

While this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. Various modifications and combinations of the illustrative embodiments, as well as other embodiments of the invention will be apparent to persons skilled in the art upon

reference to the description. It is therefore intended that the appended claims encompass any such modifications or embodiments.

CLAIMS

1. An implantable endoluminal prosthesis adapted for placement at a bifurcation site within a body, said device having at least two segments, at least one of said segments having structural properties different from another of said segments.

2. The endoluminal prosthesis of claim 1 wherein said device comprises a main body component and a contralateral leg component.

3. The endoluminal prosthesis of claim 1 wherein at least one of said components has a segment having an axial stiffness that is higher than adjacent segments.

4. The endoluminal prosthesis of claim 3 wherein said segment of higher axial stiffness comprises at least one extended strut.

5. The endoluminal prosthesis claim 1 wherein said device further comprises:

a stent member having an outer surface;

a generally tubular graft member;

a tape member covering only a portion of said outer surface of said stent member and securing the stent member and graft member to one another, said tape member having a different width in at least one of said segments.

6. A stent-graft component comprising:

a graft member having a single-lumen graft section and a bifurcated graft section, said bifurcted graft section having two separate lumen;

a single lumen stent section secured to at least a portion of the periphery of said graft section, said single lumen stent section extending over at least a portion of said bifurcated graft section.

7. The stent-graft of claim 6 wherein greater than 180 degrees of the periphery of each of said two separate lumen are contacted by said distal stent section.

8. The stent-graft of claim 6 wherein at least one of said separate lumen terminates distally at a leg hole and said stent-graft further comprises a ring for support of said leg hole.

9. The stent-graft of claim 8 wherein said ring comprises an undulating wire.

10. The stent-graft of claim 8 wherein said stent-graft further comprises a radiopaque wire around the outside diameter of said leg hole.

11. The stent-graft of claim 10 wherein said separate lumen are a contralateral leg lumen having a receiving hole and a ipsalateral leg lumen having an ipsalateral leg hole, said independent wire ring being secured at or near said receiving hole.

12. The stent-graft of claim 8 wherein said stent member further comprises at least one anchor for securing said stent-graft to a vessel wall.

13. The stent-graft of claim 12 wherein said anchor comprises a stent apex bent at an angle to an outer surface of said graft.

14. The stent-graft of claim 12 wherein said anchor comprises at least one wire segment bent at an angle to an outer surface of said graft.

15. A stent-graft section comprising:

a generally tubular stent member section having an inner surface and an outer surface;

a multilumen graft section secured to at least one of said inner and outer surfaces of said tubular stent member.

16. The stent-graft section of claim 15 wherein said graft section is bifurcated into two lumen and is attached to said inner surface.

17. The stent-graft section of claim 16 wherein said two lumen are secured to each other by at least one suture.

18. A stent section comprising a wire structure having undulations, said undulations characterized by an alternating series of upper apexes and lower apexes, said wire structure arranged in a helical configuration having at least a first turn and a second turn, said first turn having at least one lower apex which extends to substantially meet a lower apex of said second turn.

19. The stent section of 18 wherein said upper and lower apexes of said of said first turn are in-phase with said apexes of said second turn.

20. The stent section of 18 wherein said stent section comprises multiple turns, each one of said multiple turns having at least one lower apex which extends to substantially meet a lower apex of an adjacent turn.

21. The stent section of 20 wherein the extended apex of each turn is spaced one undulation from the extended apex of a successive turn.

22. The stent section of 18 further comprising a graft member attached to said wire structure.

23. A modular prosthesis adapted for placement at a bifurcation site within a body, said prosthesis comprising:

a main body component having an extended cylindrical female receiving portion; and

a leg component having a mating cylindrical male portion, adapted for attachment to said extended cylindrical female receiving portion.

24. The modular prosthesis of claim 23 wherein said male portion is attached within said female portion by an interference fit.

25. The modular prosthesis of claim 24 wherein cylindrical male portion has a first diameter and said cylindrical female portion has a diameter smaller than said first diameter.

26. The modular prosthesis of claim 24 wherein said female receiving portion further comprises a zone of decreased diameter in the vicinity of an anchoring ring, said anchoring ring being attached to said female receiving portion.

27. The modular prosthesis of claim 24 wherein said female receiving portion further comprises an internal folded flap of graft material, said flap creating a zone of reduce diameter within the female receiving portion.

28. The modular prosthesis of claim 27 wherein said flap further includes an anchoring ring.

29. A self-expanding stent-graft device comprising a stent member and a graft member, said stent member having a terminating end in the form of a turn of an undulating wire; said graft component being attached to said stent component, said graft component having a scalloped shape at an end which corresponds to the shape of said stent end.

30. A method of forming a bifurcated graft member comprising the steps of:

heat bonding a first tube section to a second tube section such that a common septum is formed and removing said septum to form a smooth bifurcation.

31. A prosthesis anchor for securing an outer surface of an endoluminal prosthesis to a lumen wall, said anchor comprising a wire portion extending angularly in a first direction from said surface, said wire portion being pivotably coupled relative to said surface.

32. The prosthesis anchor of claim 31, wherein said anchor further comprises a second wire portion extending angularly in a second direction from said surface, said second wire portion coupled to said first wire portion such that displacement of said second wire towards said surface urges said first wire away from said surface.

33. The prosthesis anchor of claim 32, wherein first wire portion and said second wire portion are constructed a continuous wire.

33. The prosthesis anchor of claim 32, wherein said endoluminal prosthesis comprises a wire stent structure and said anchor is pivotably coupled under at least one of said stent wires.

34. The prosthesis anchor of claim 32, wherein said first and second directions are substantially 180 degrees apart.

ABSTRACT OF THE DISCLOSURE

The invention consists of an endoluminal prosthesis adapted for placement at a bifurcation site within the body. The stent or stent-graft may be constructed to have segments of differing structural properties. A section of the stent-graft may be constructed to have a single-lumen tubular stent member covering a multilumen graft member. The stent-graft may comprise at least two modular components adapted for in situ assembly. An extended cylindrical interference fit may be used to seal the modular components.

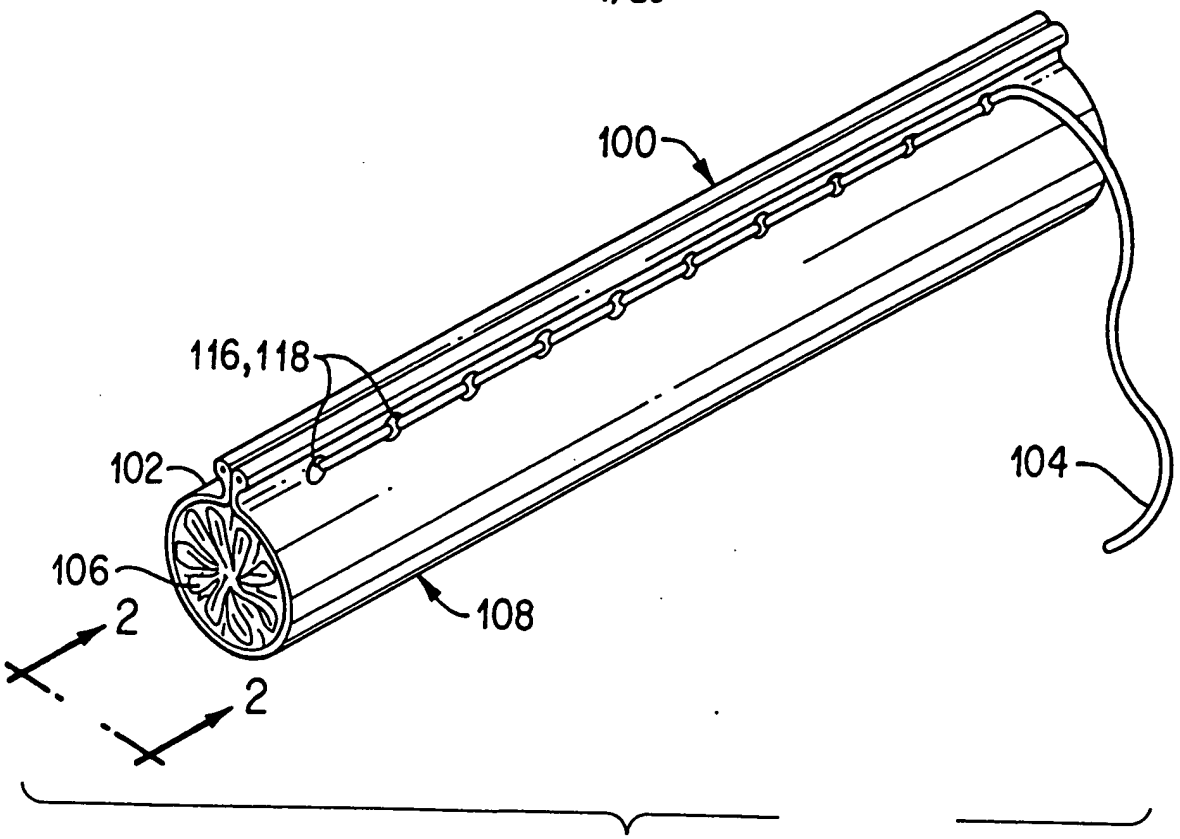


FIG. 1

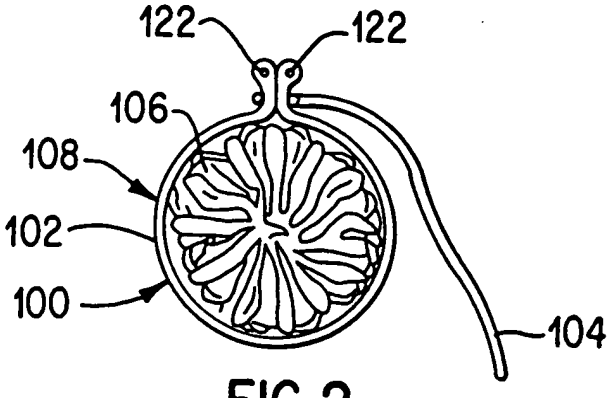


FIG. 2

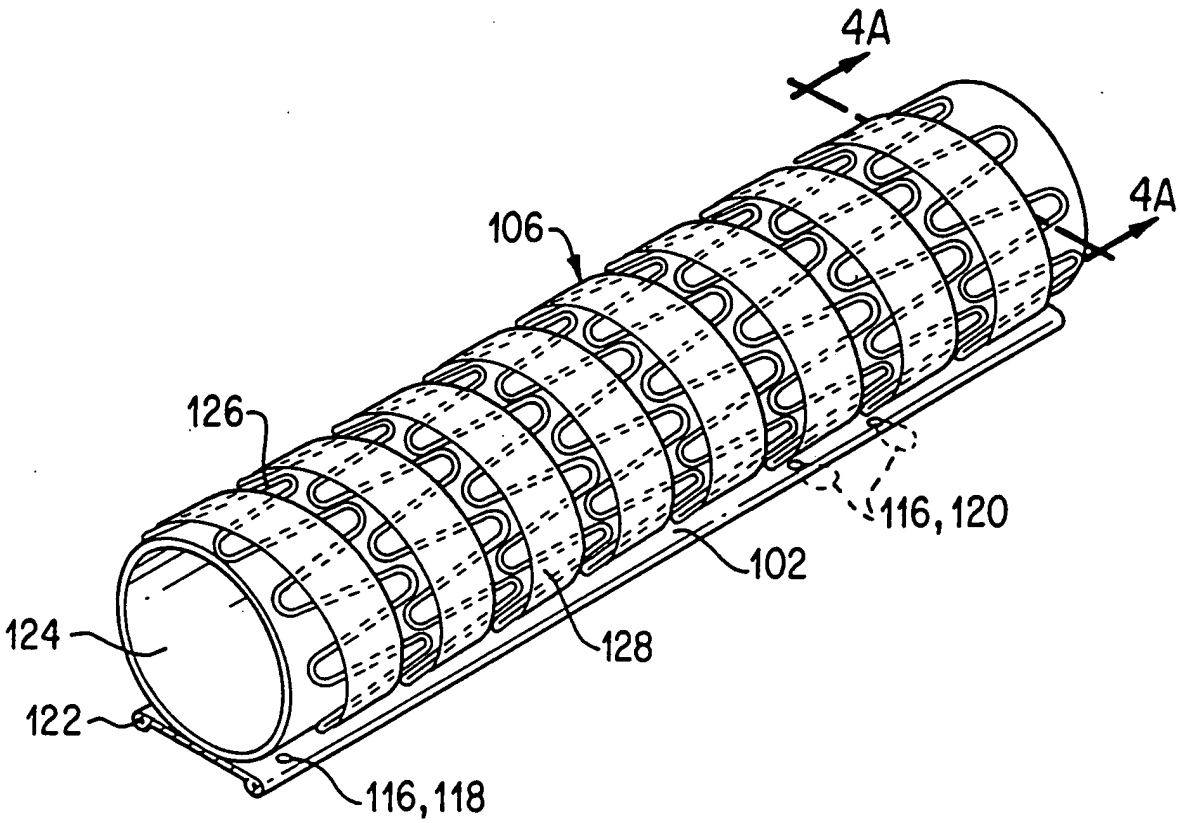


FIG. 3

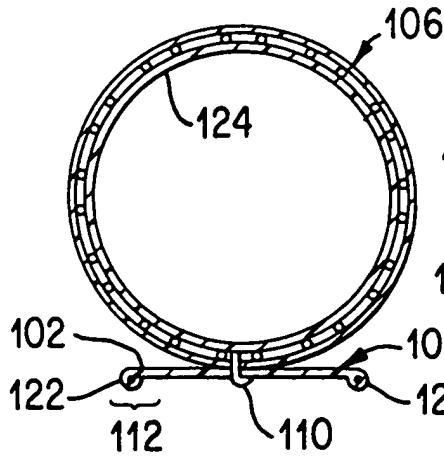


FIG. 4A

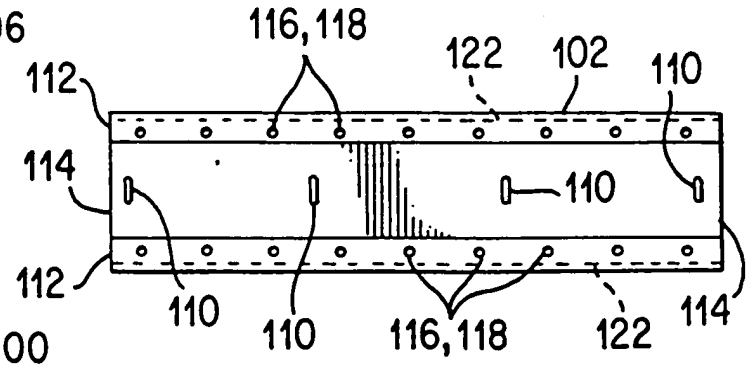


FIG. 4B

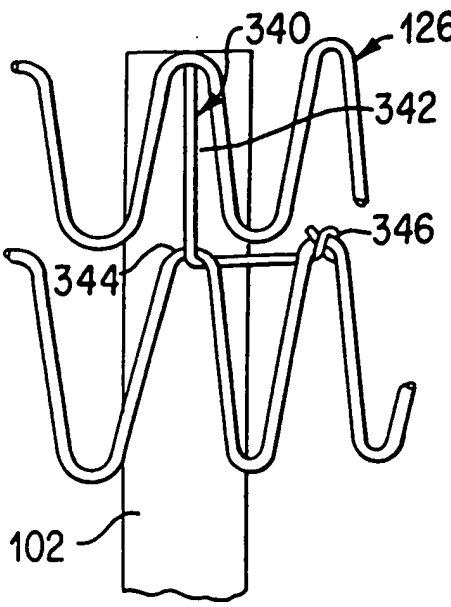


FIG.5A

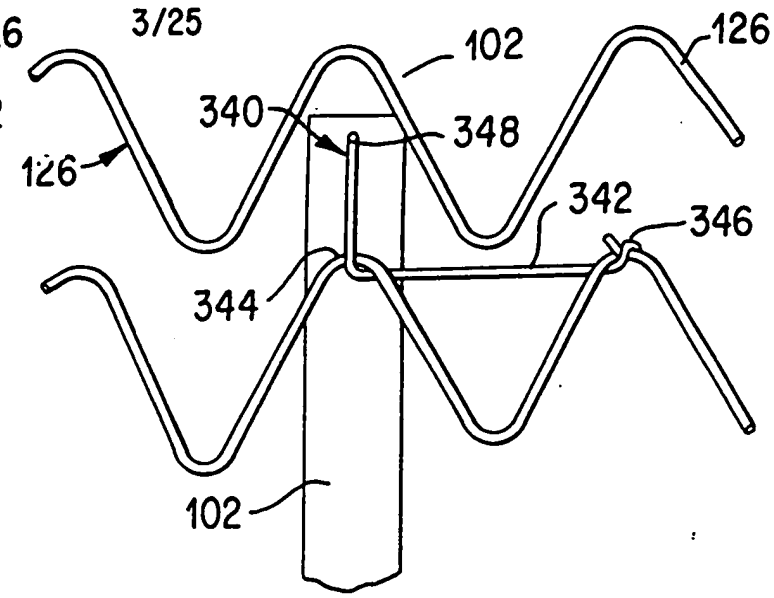


FIG.5B

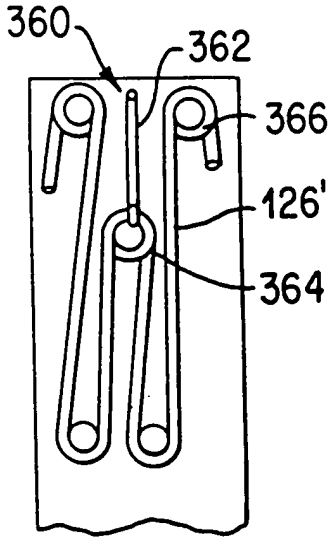


FIG.5C

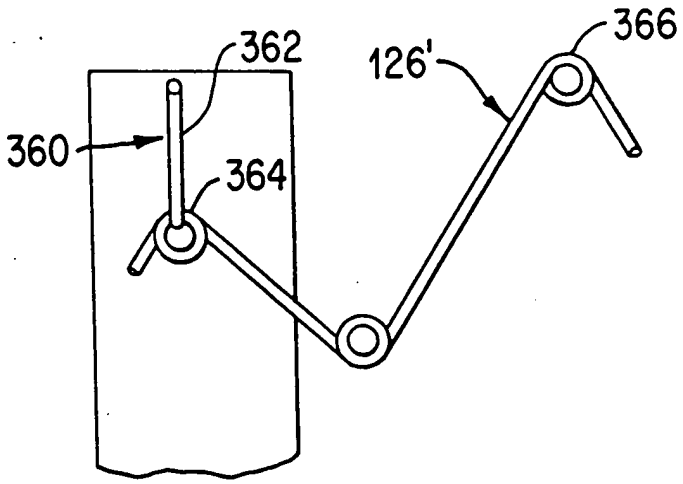


FIG.5D

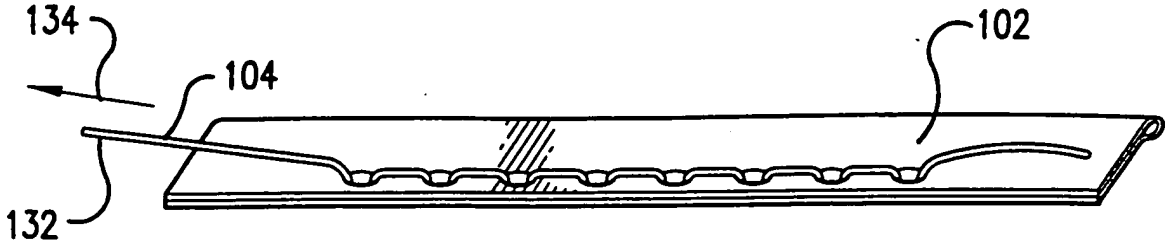


FIG.7A

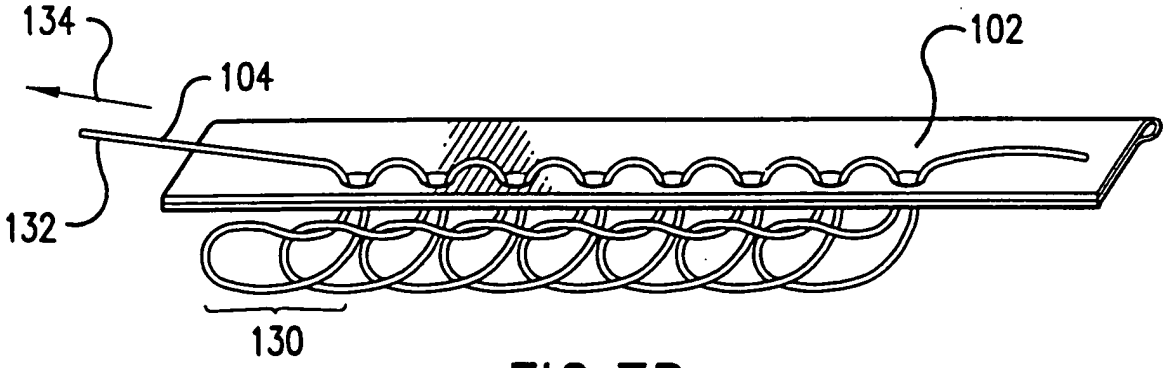


FIG.7B

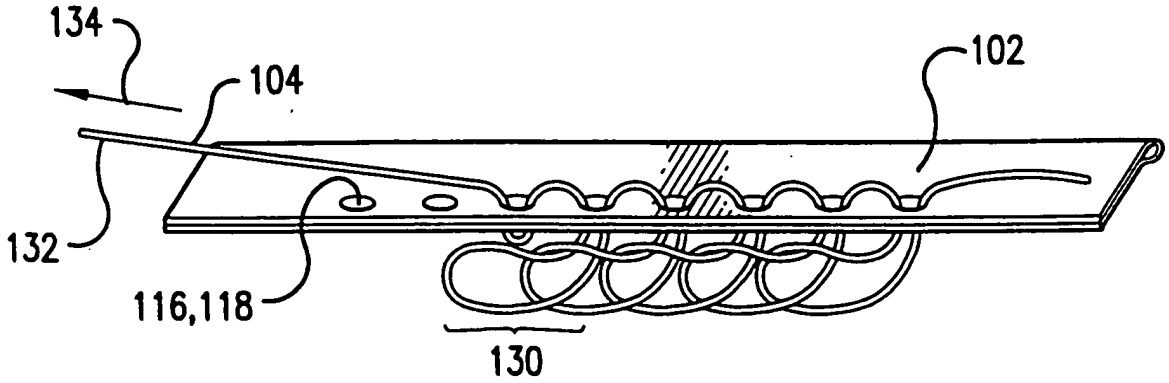


FIG.7C

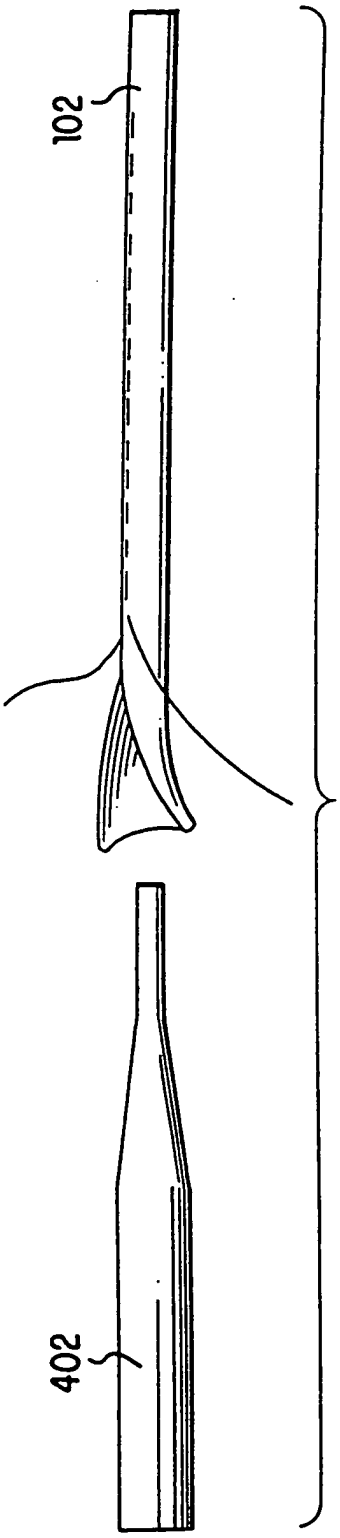


FIG. 8A

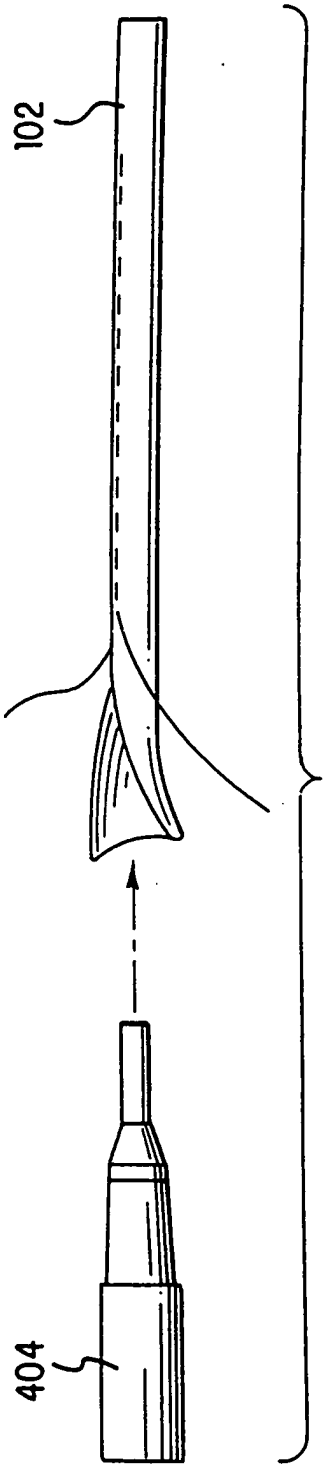


FIG. 8B

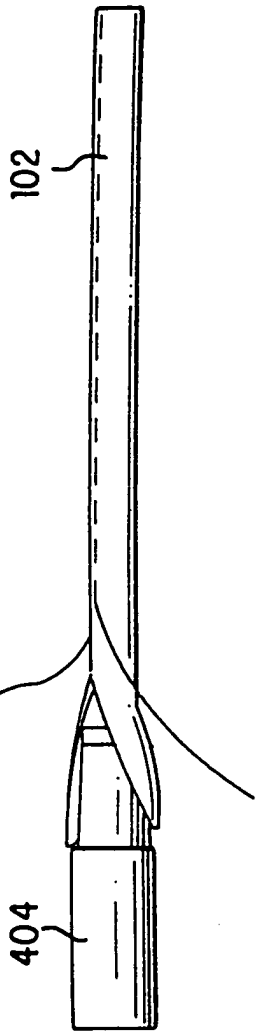


FIG. 8C

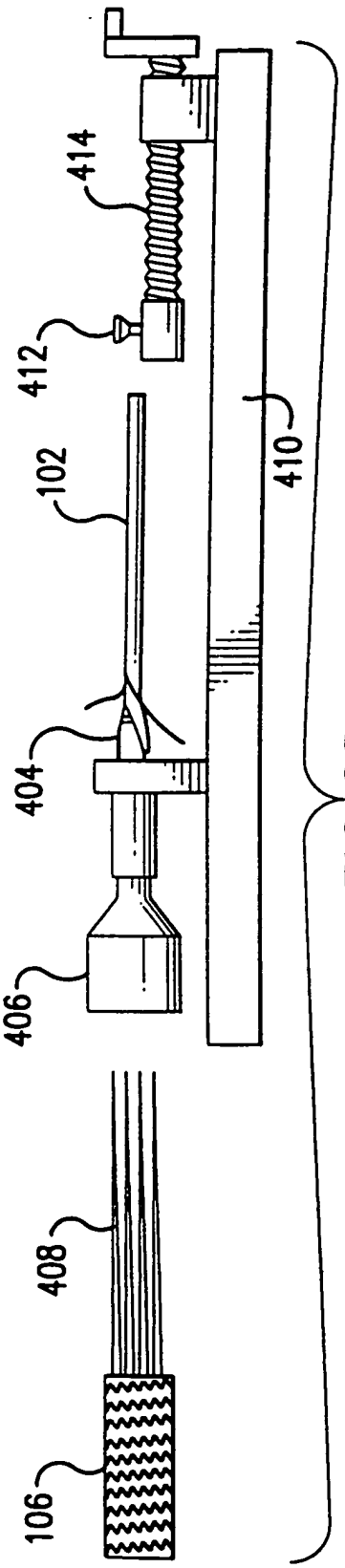


FIG.8D

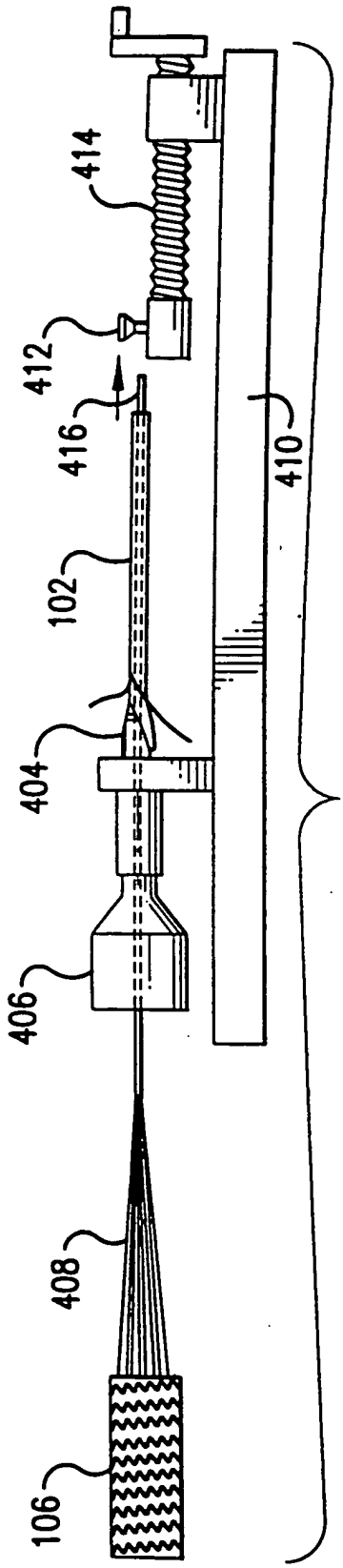


FIG.8E

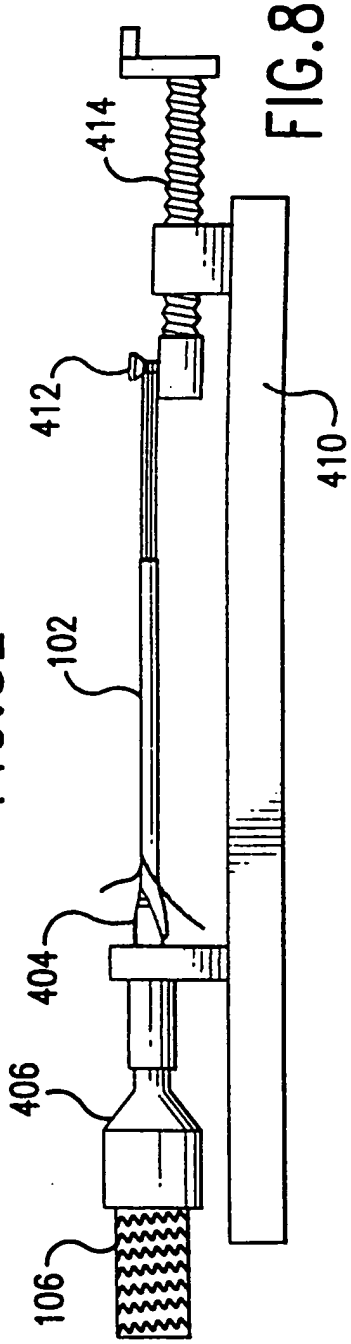


FIG.8F

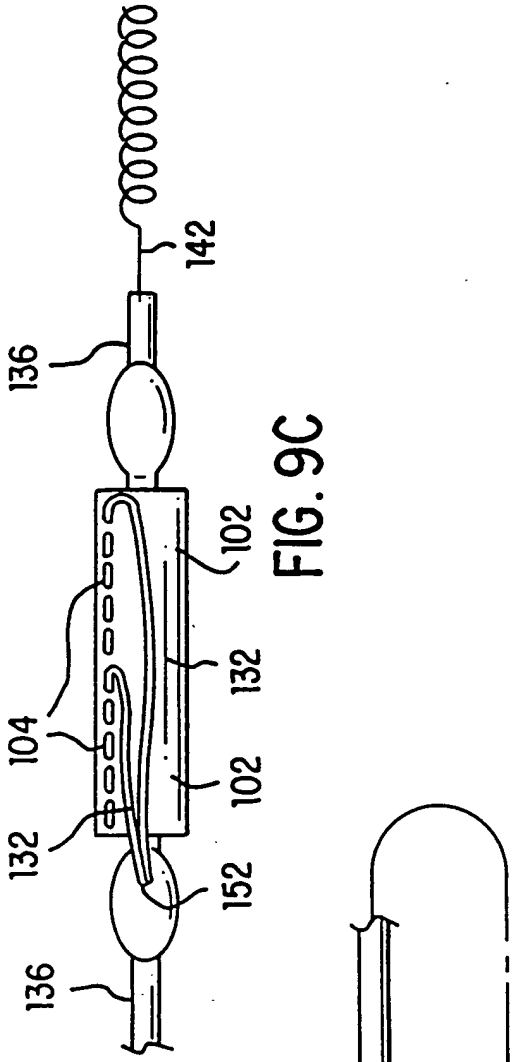


FIG. 9C

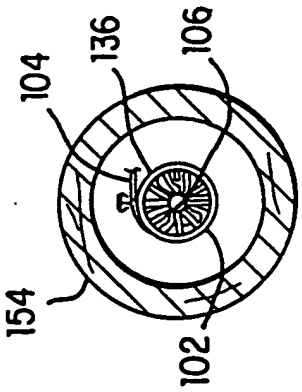


FIG. 9B

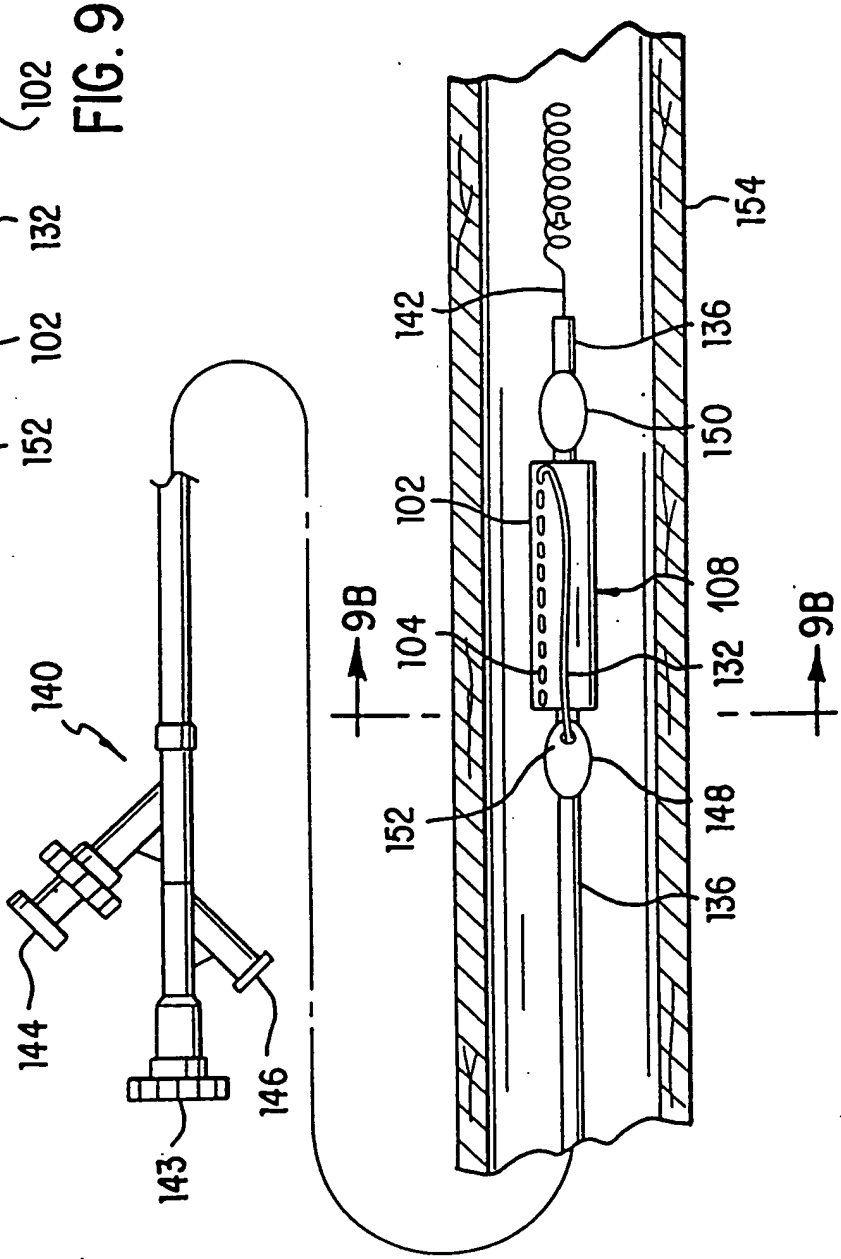


FIG. 9A

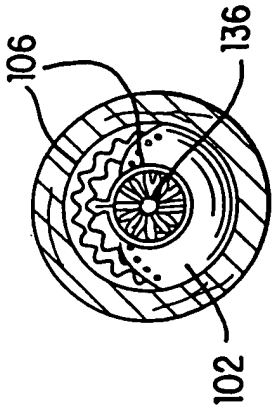


FIG.10B

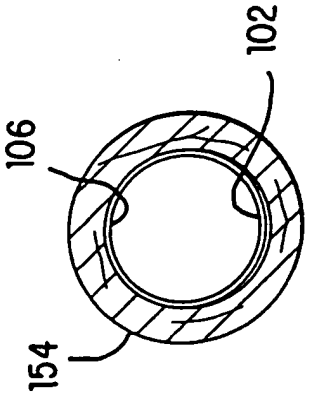


FIG.11B

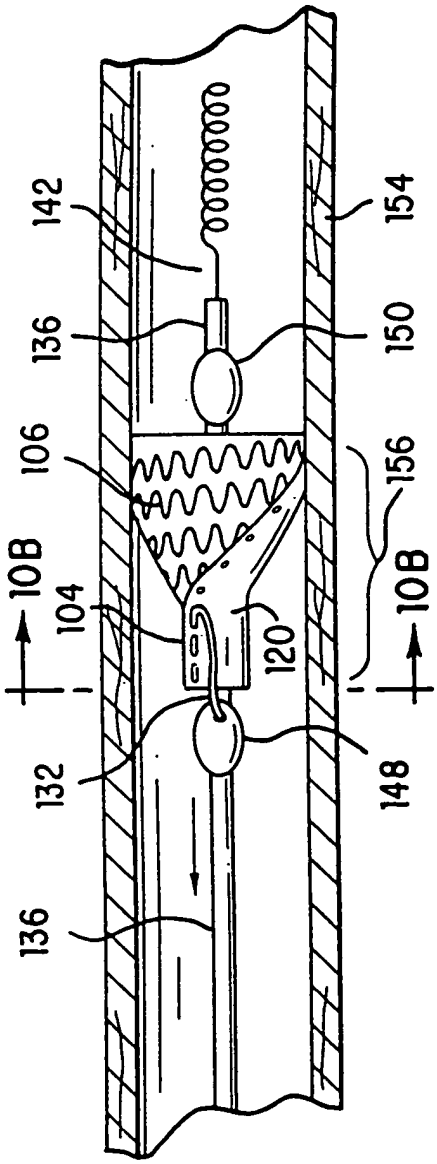


FIG. 10A

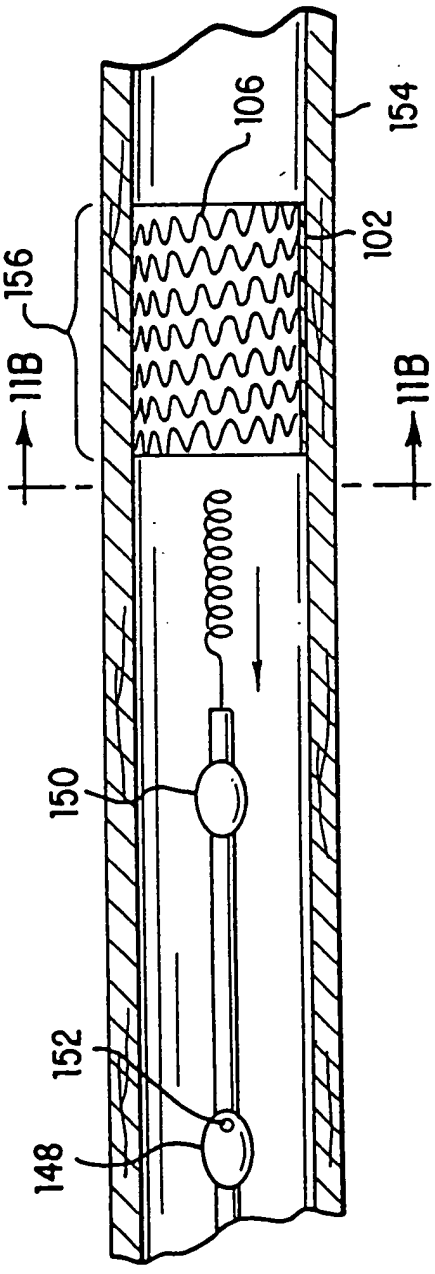


FIG.11A

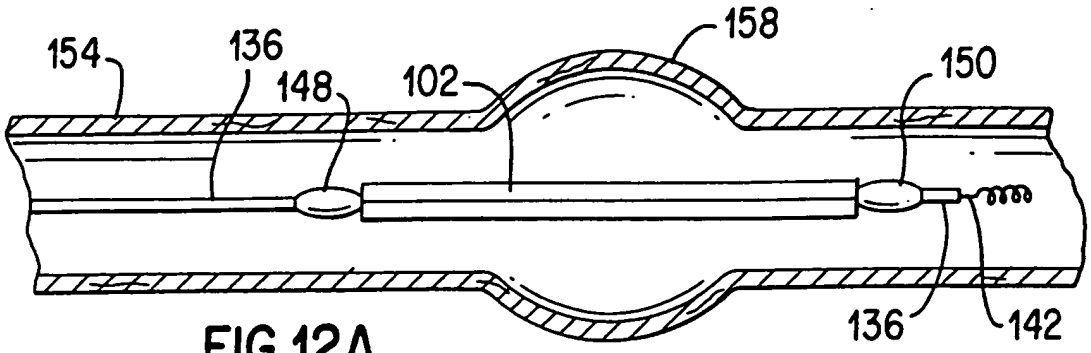


FIG.12A

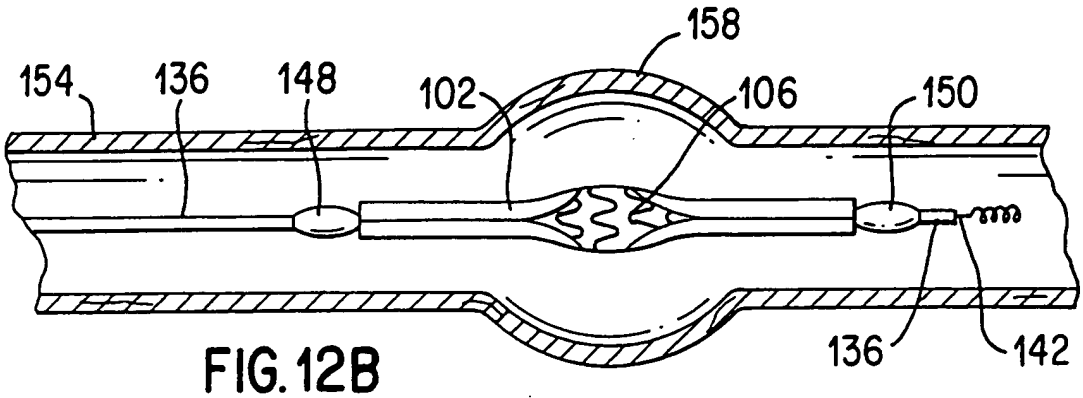


FIG.12B

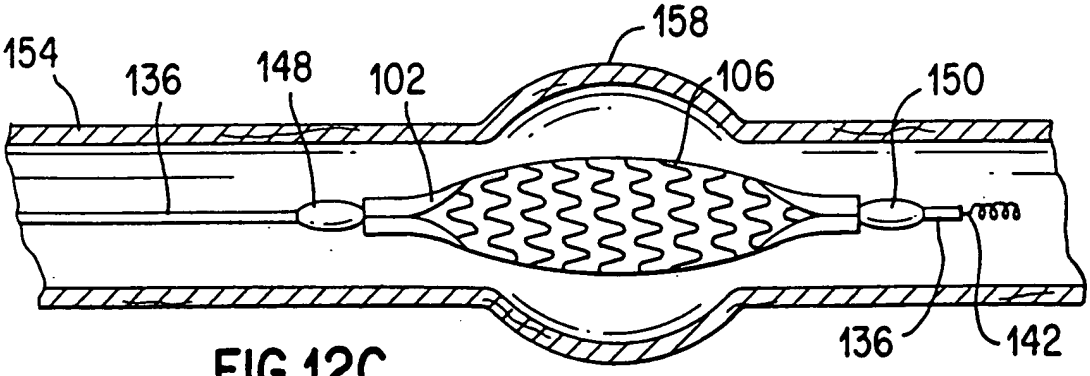


FIG.12C

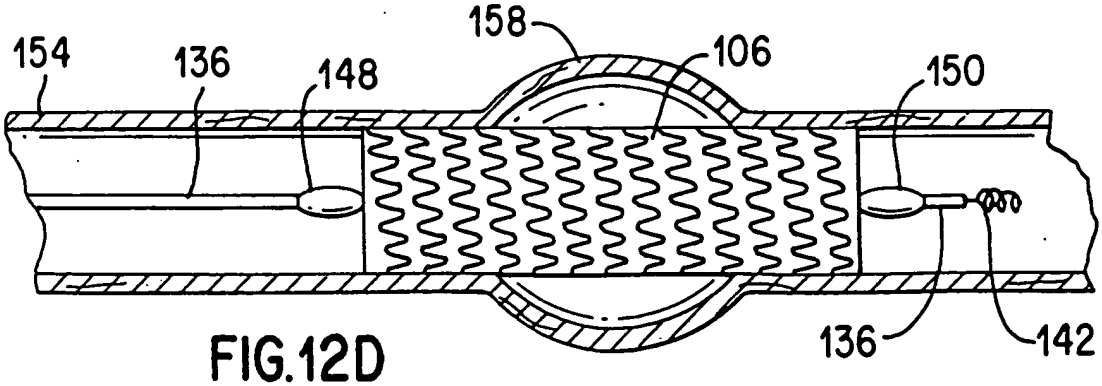


FIG.12D

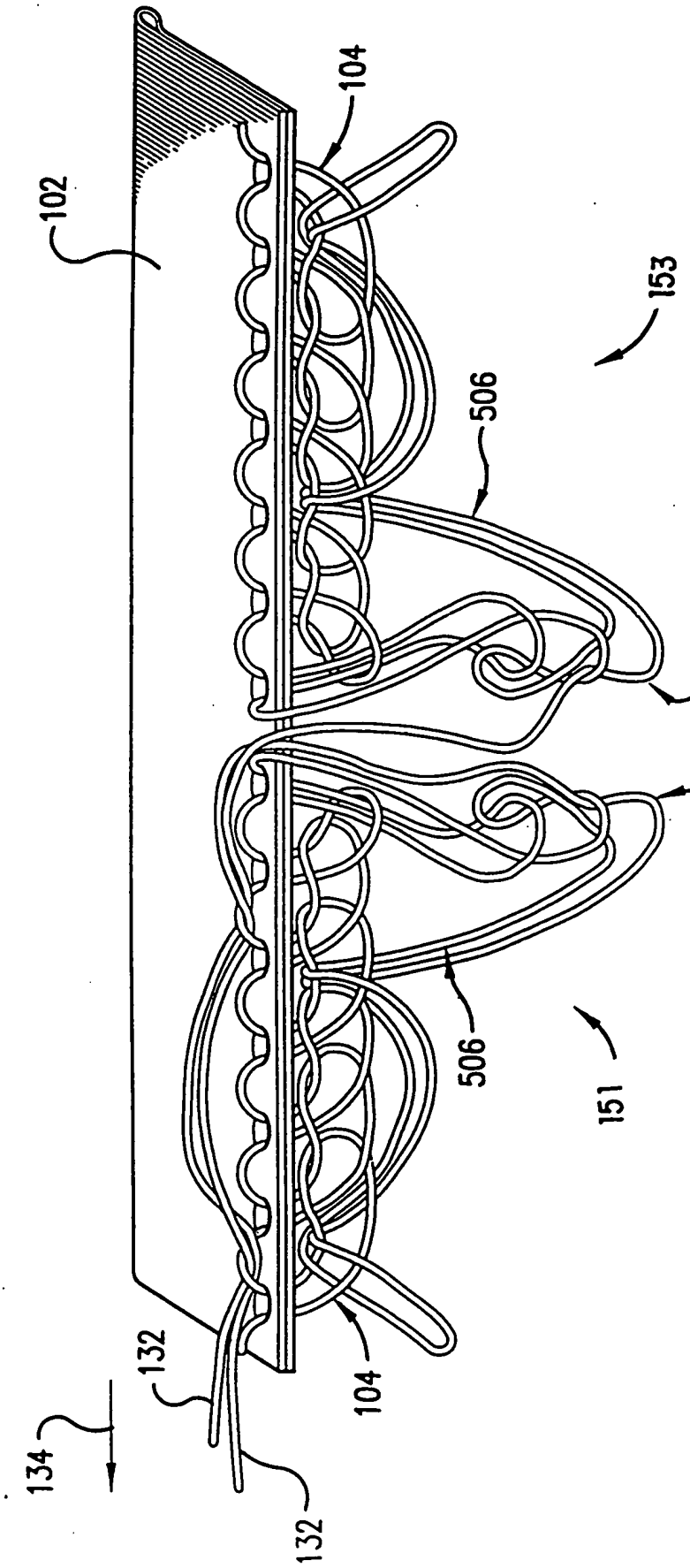


FIG.13

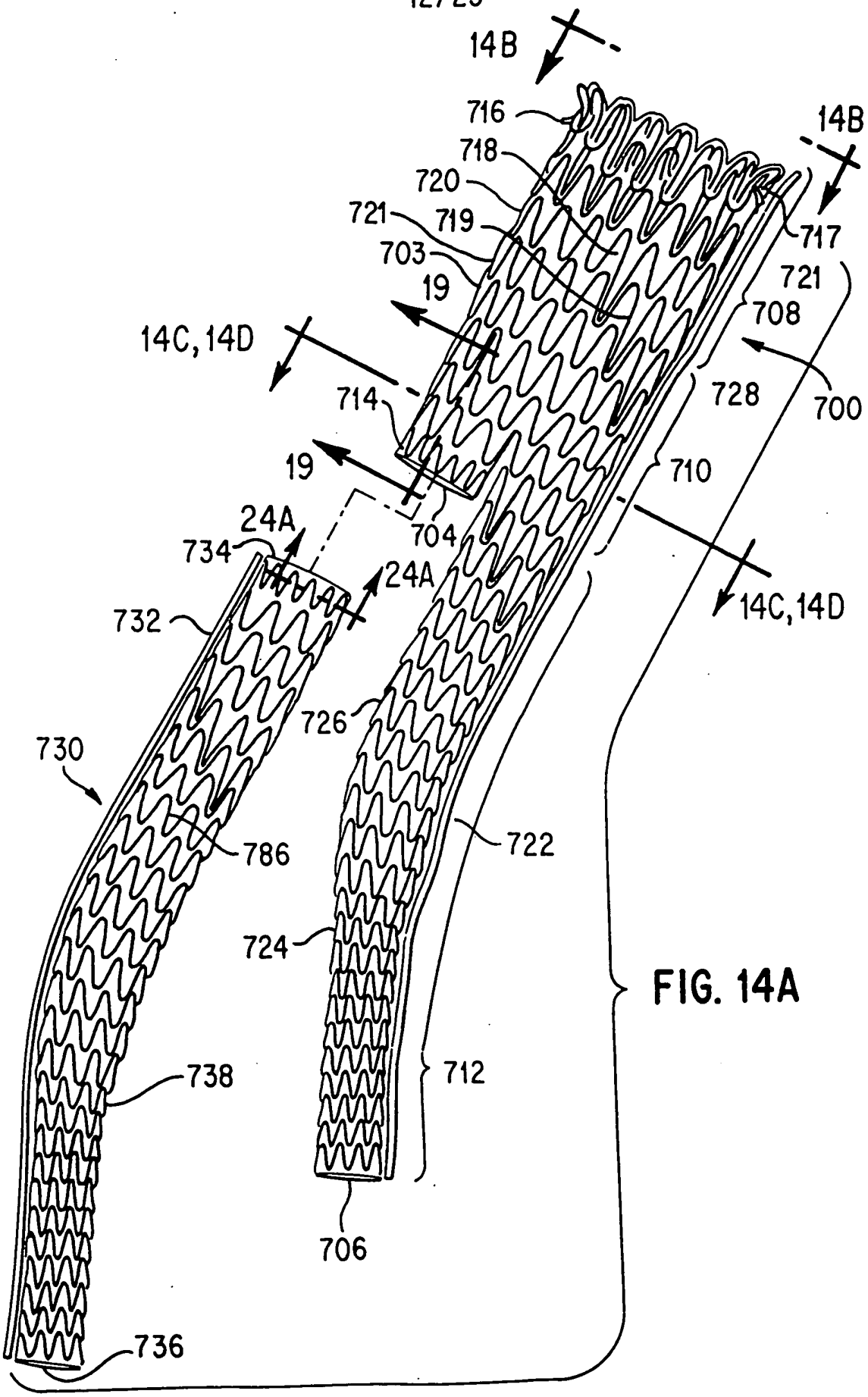

14B
716
718
720
721
719
703
19
14C, 14D
714
19
24A
734
24A
732
730
786
738
736
726
724
706
722
712
710
704
728
708
721
717
14B
700
14C, 14D

FIG. 14A

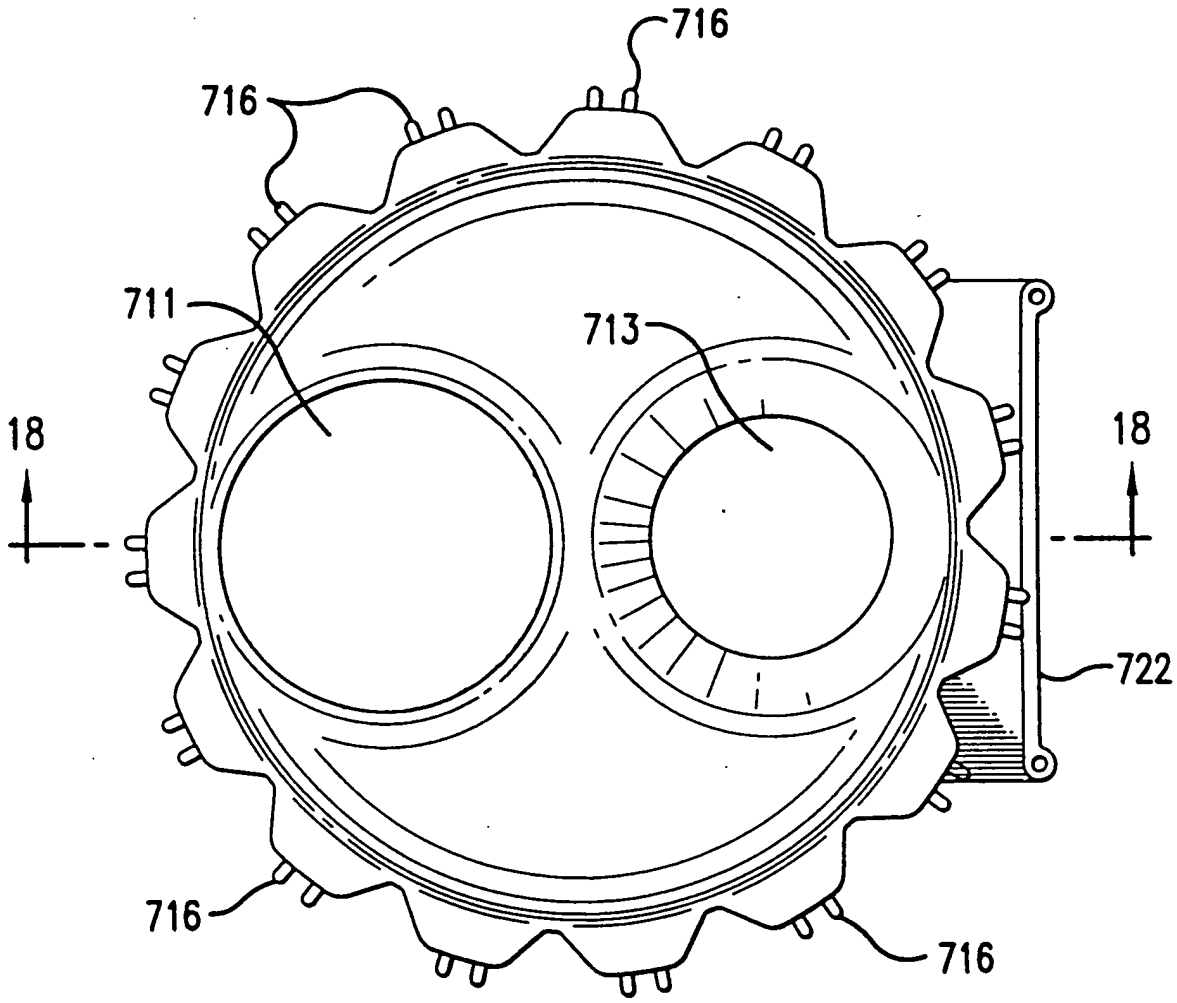


FIG.14B

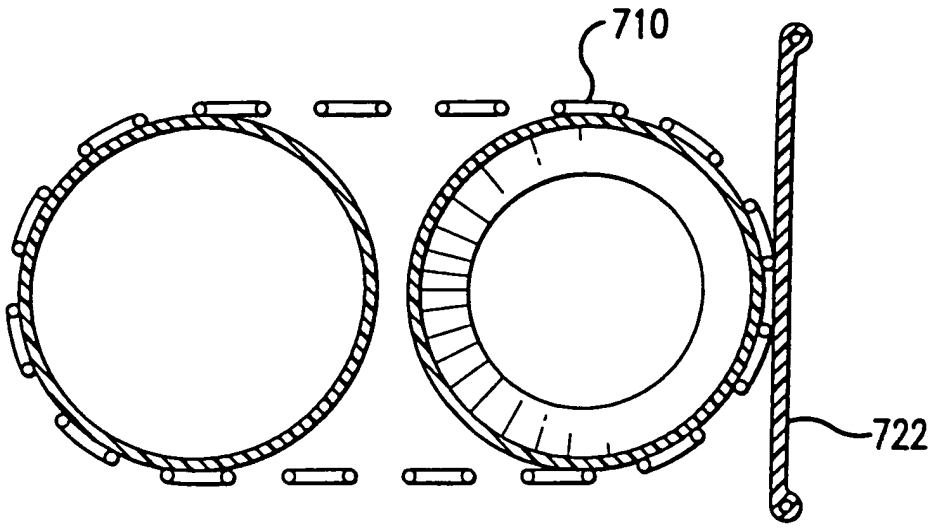


FIG.14C

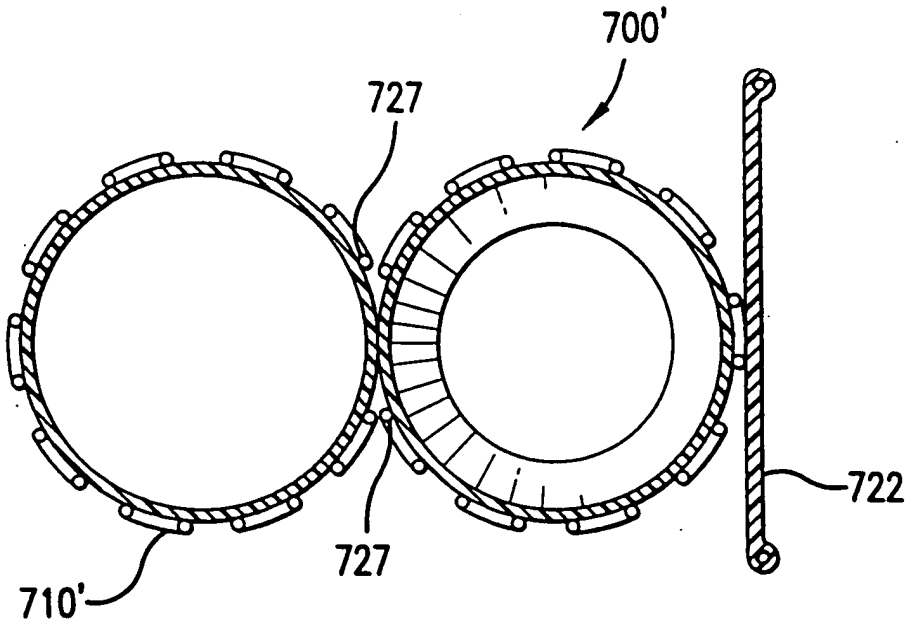


FIG.14D

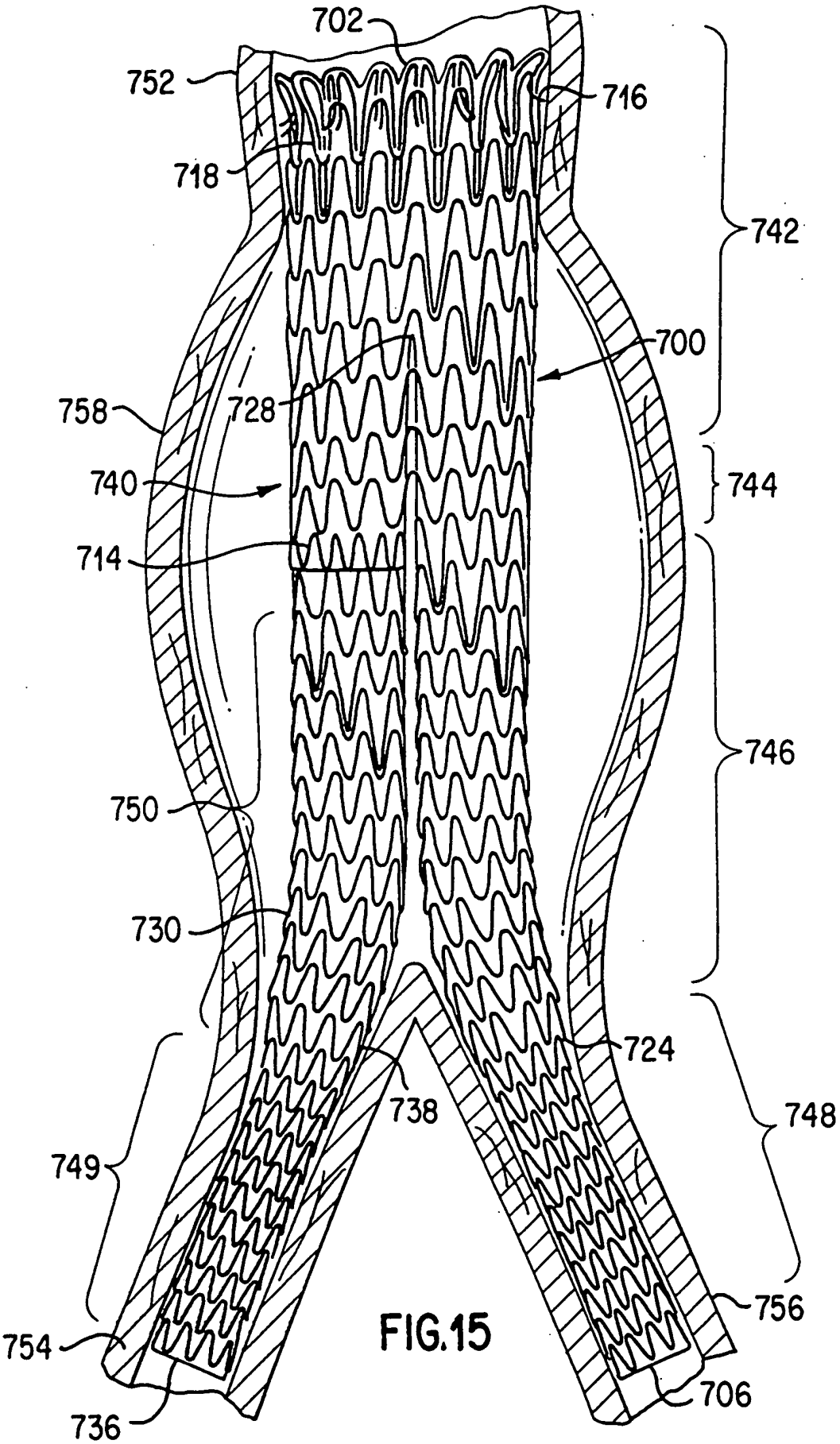

702
752
716
718
742
700
758
728
740
744
714
746
750
730
724
738
748
749
756
754
706
736

FIG.15

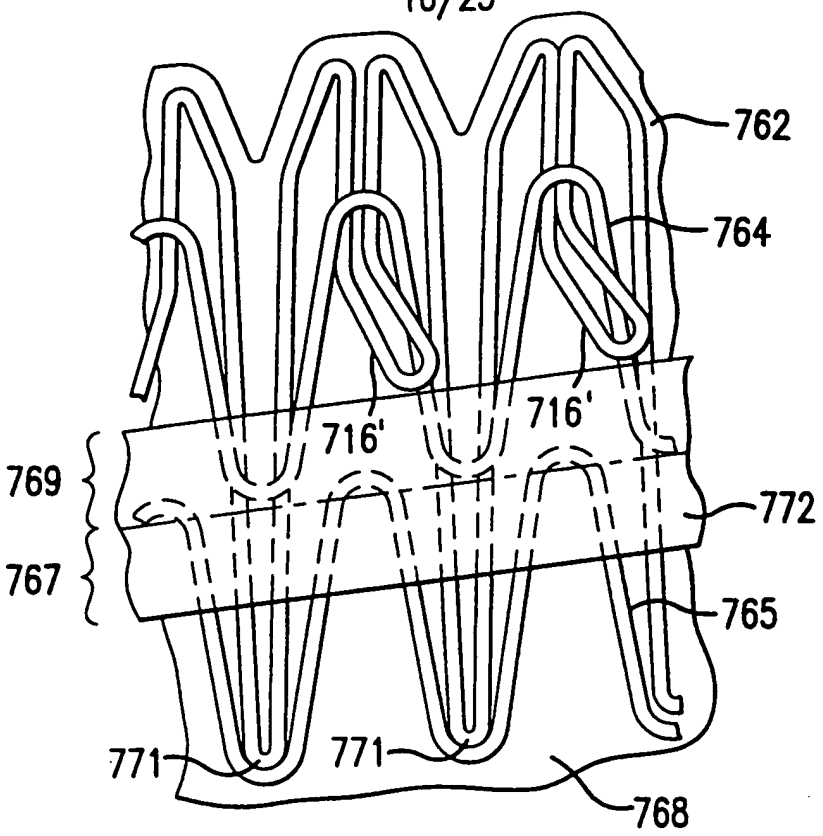

762
764
716'
716'
769
772
767
765
771
771
768

FIG.16

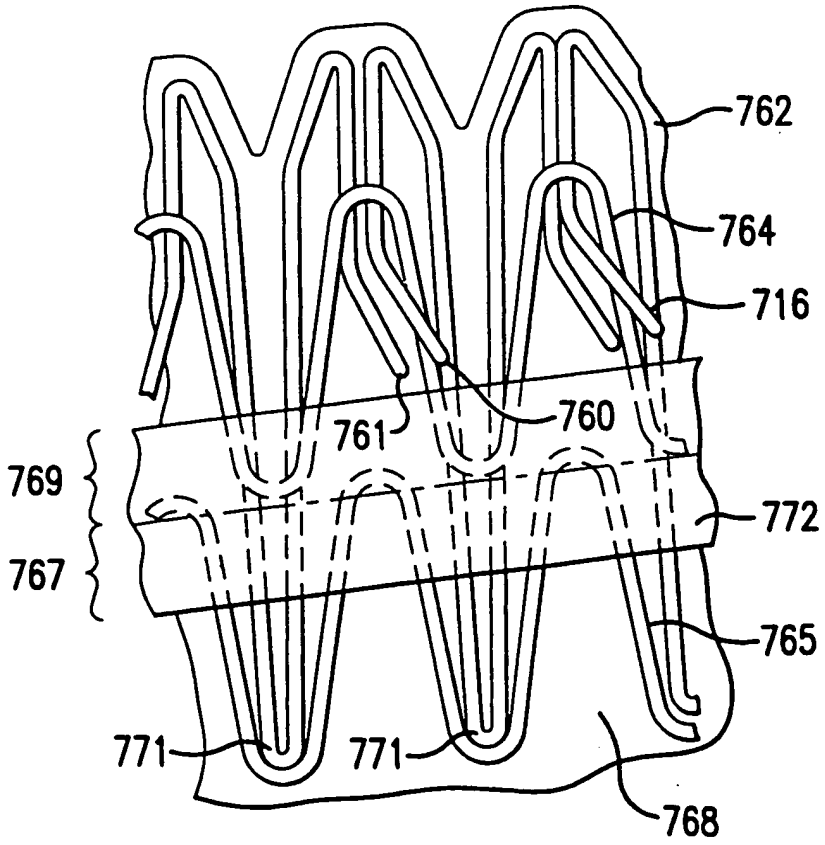

762
764
716
761
760
769
772
767
765
771
771
768

FIG.17

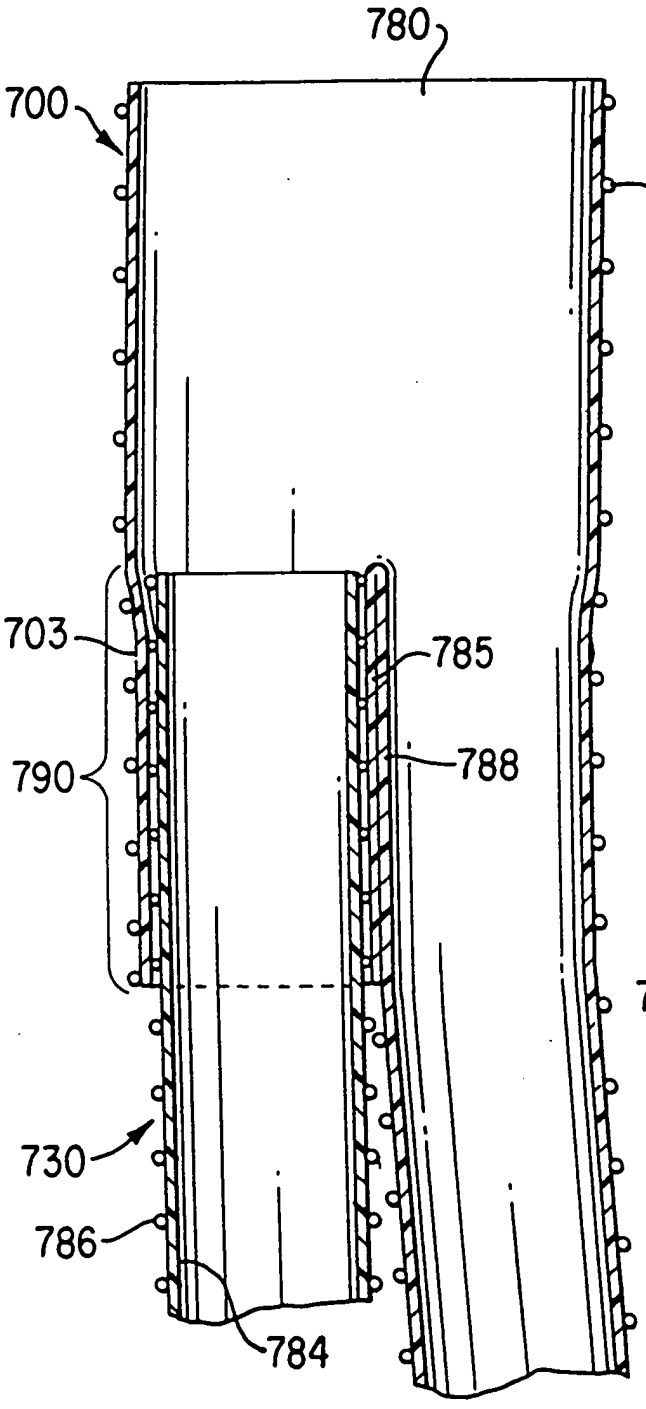


FIG. 18

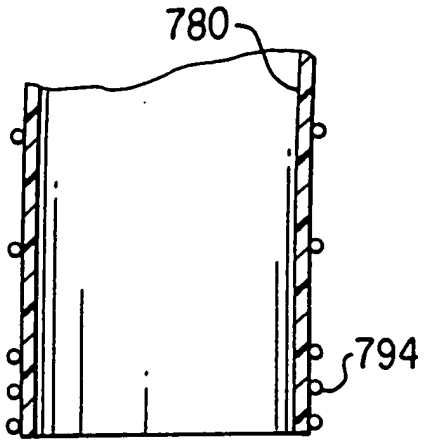


FIG. 19

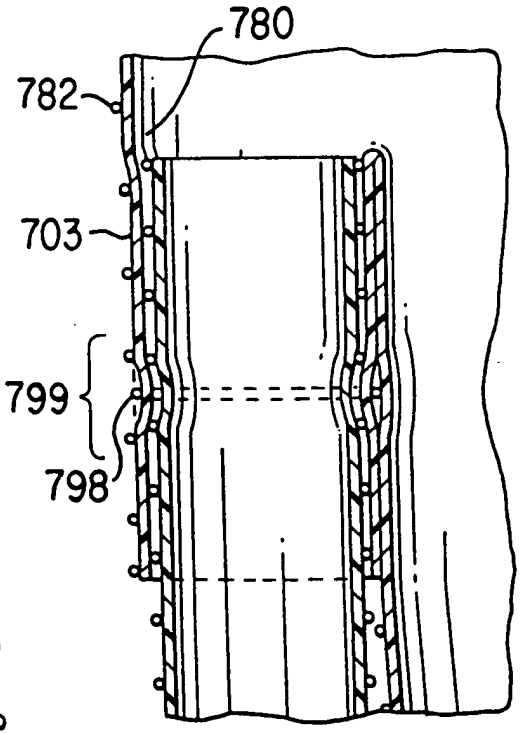


FIG. 20

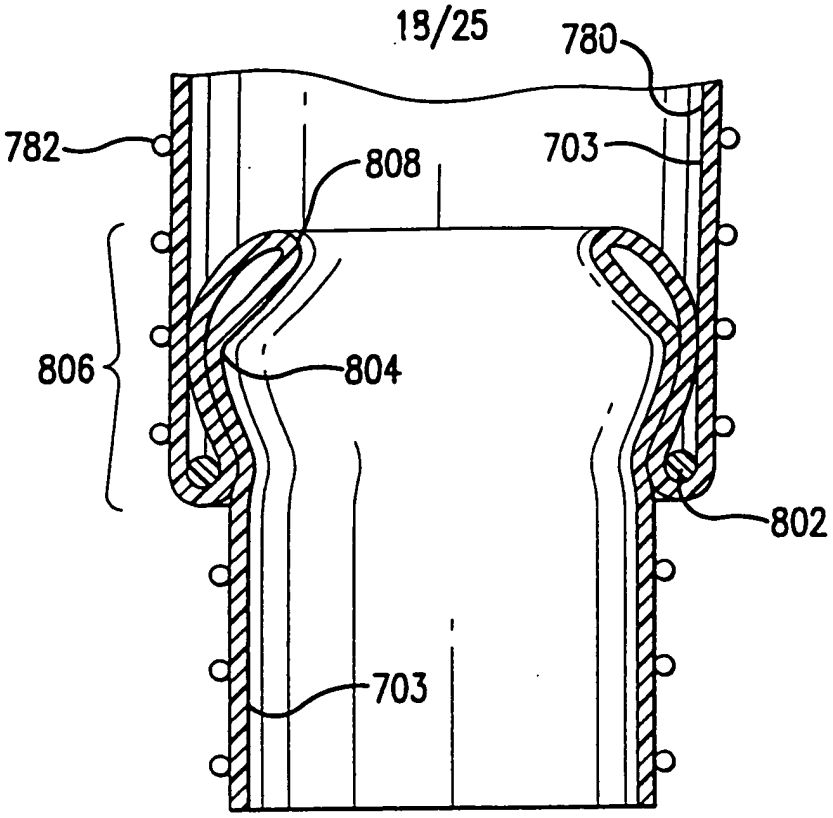


FIG.21

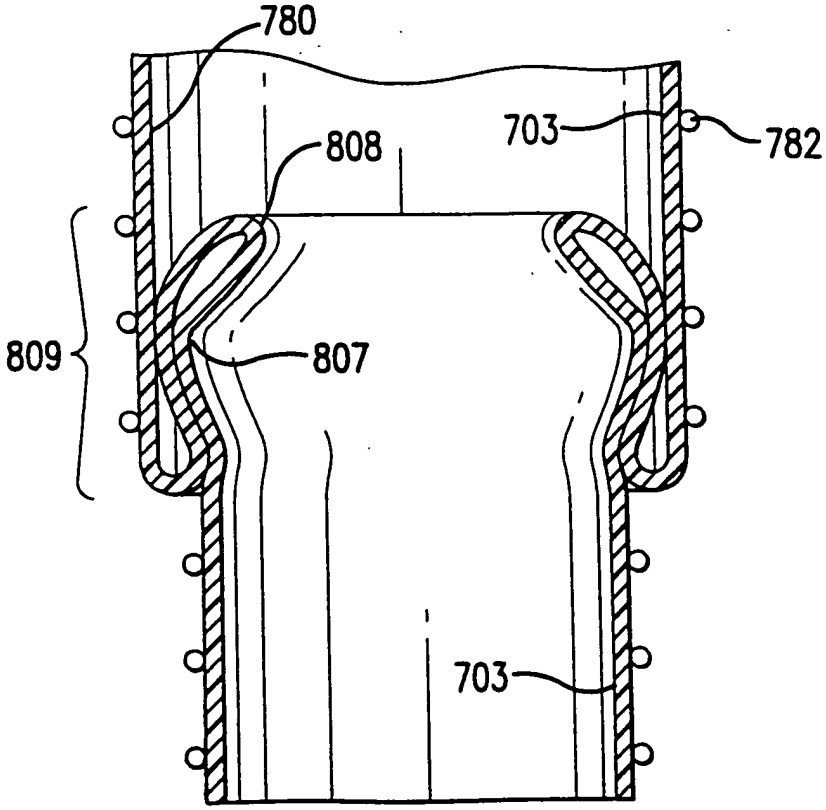


FIG.22

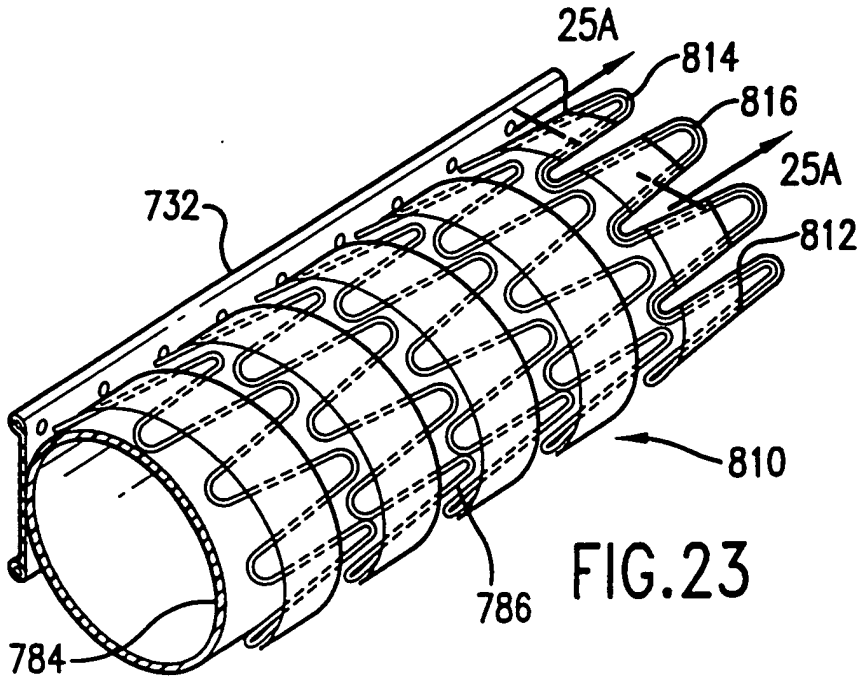


FIG.23

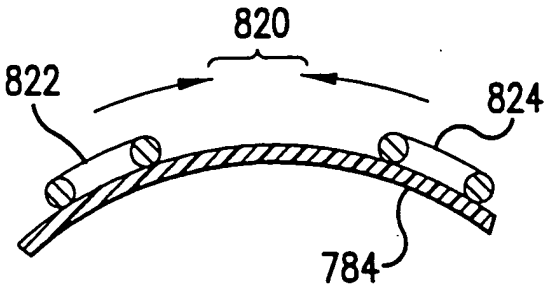


FIG.24A

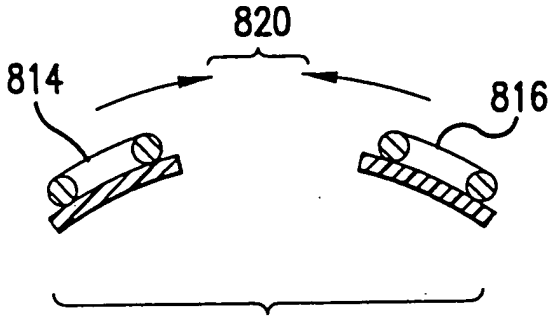


FIG.25A

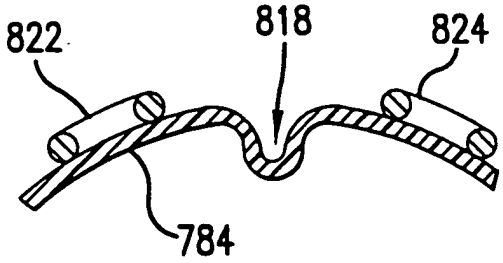


FIG.24B

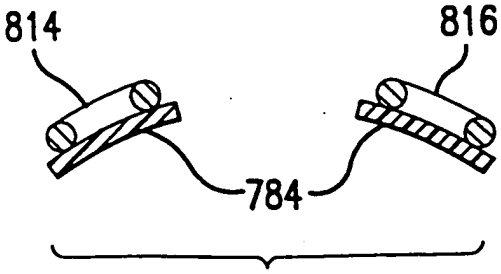


FIG.25B

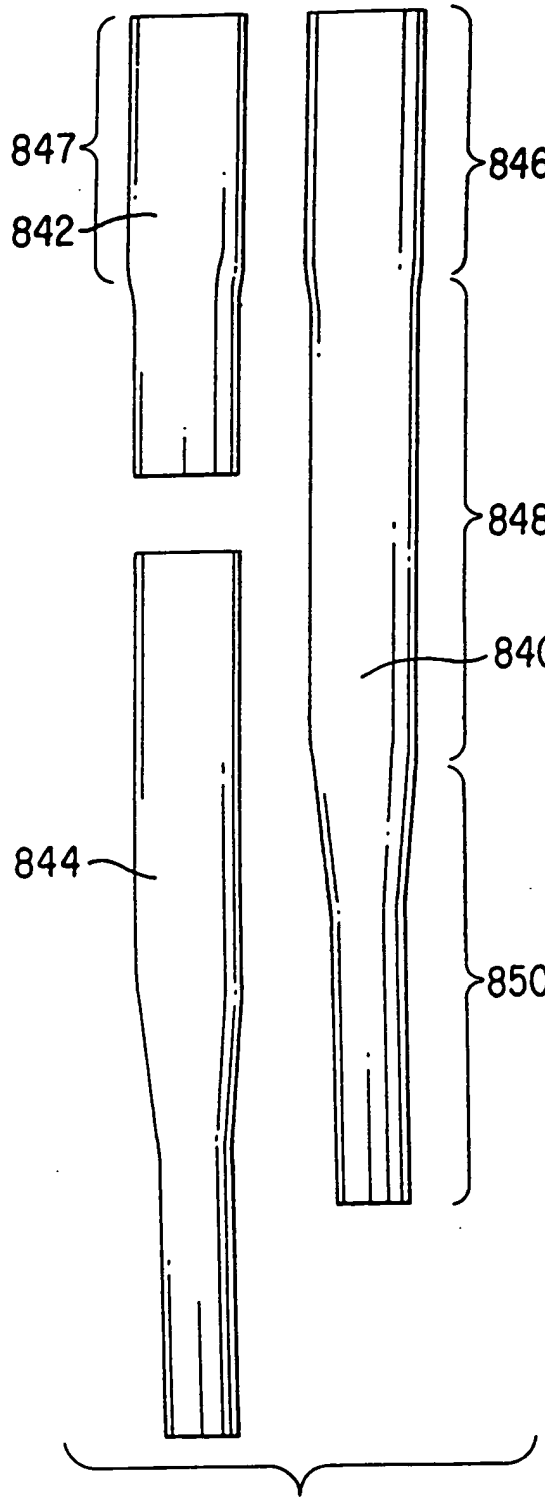


FIG. 26A

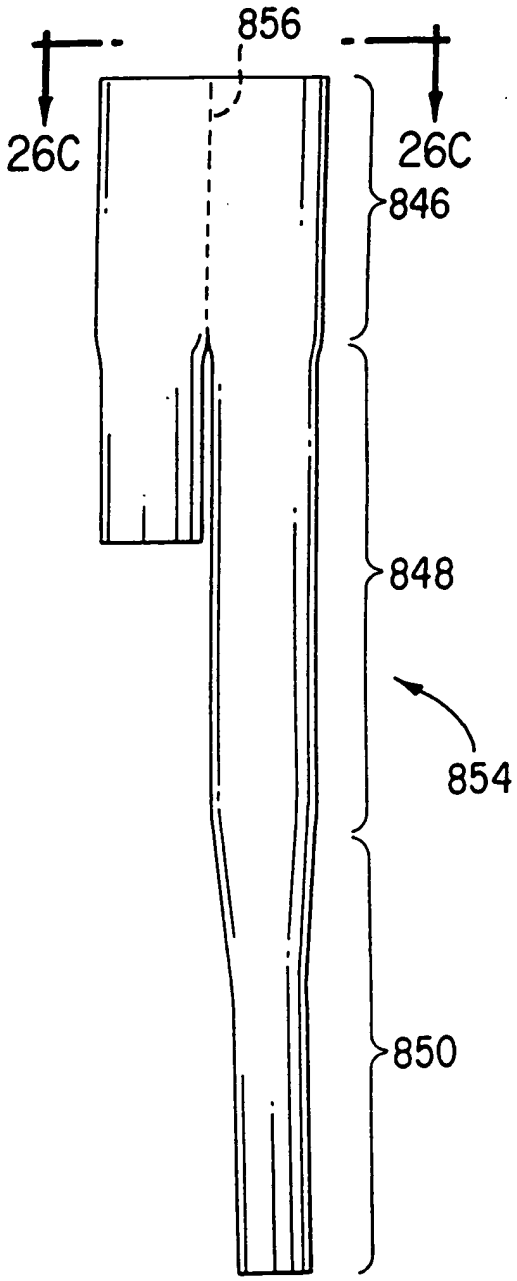


FIG. 26B

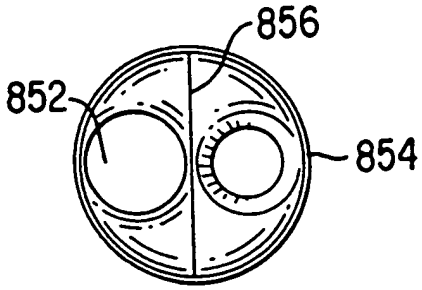


FIG. 26C

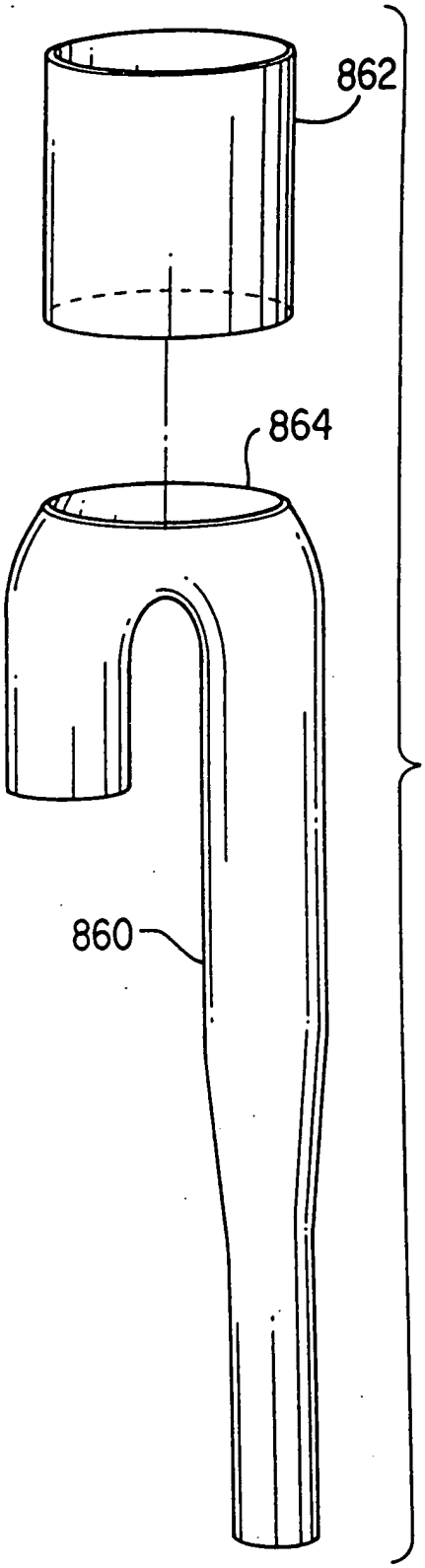


FIG. 27A

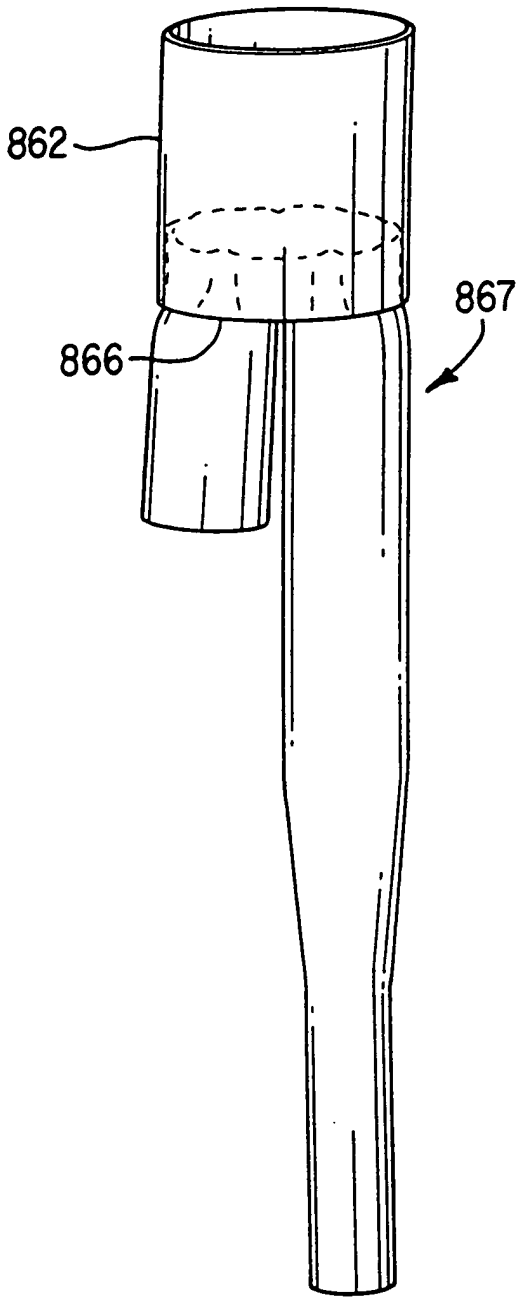


FIG. 27B

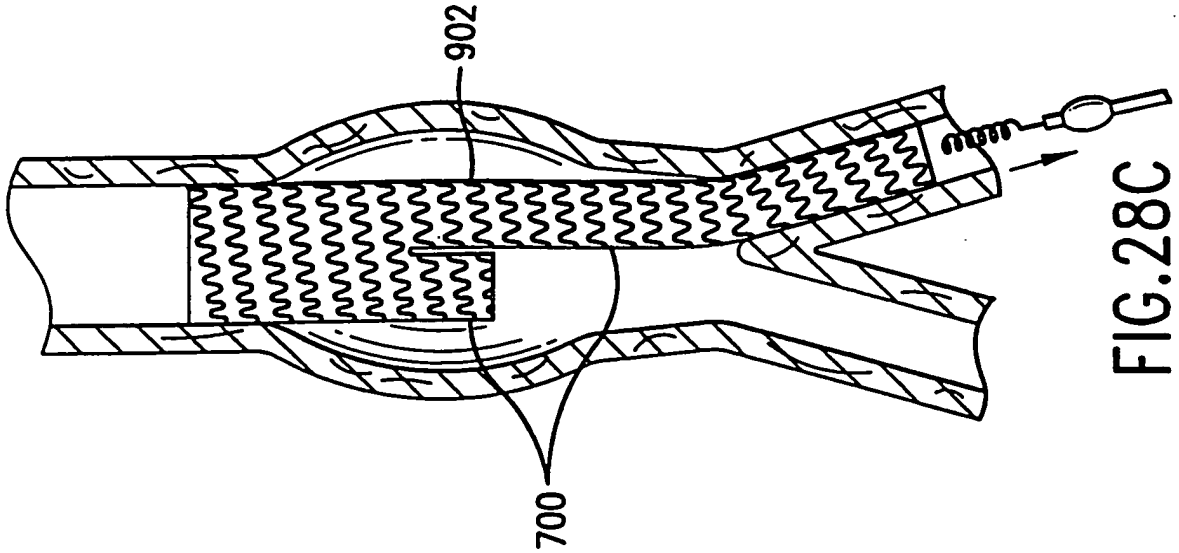


FIG.28C

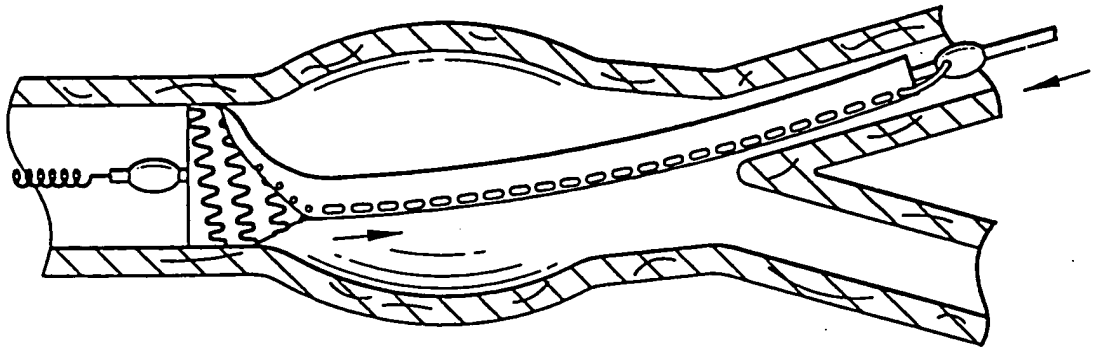


FIG.28B

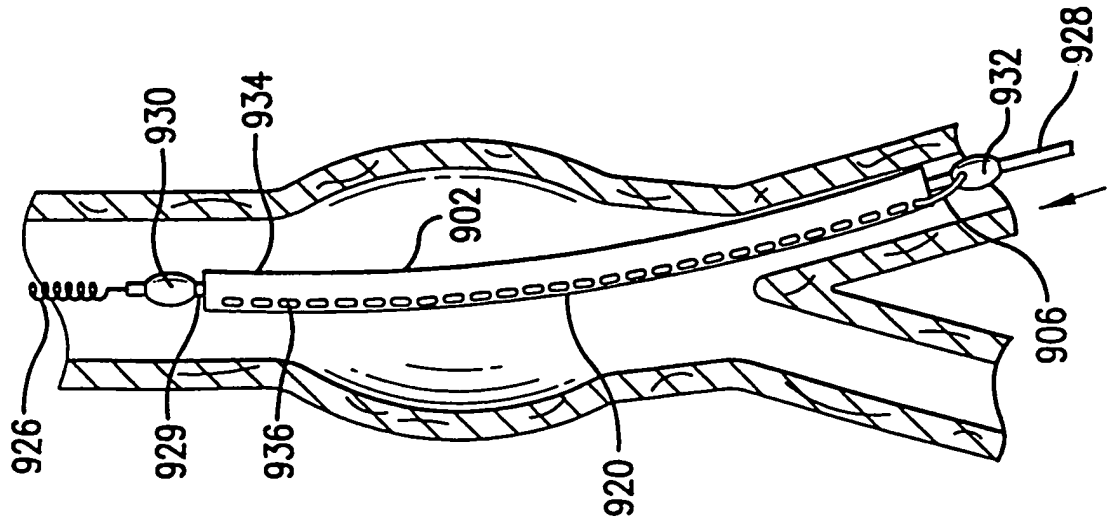


FIG.28A

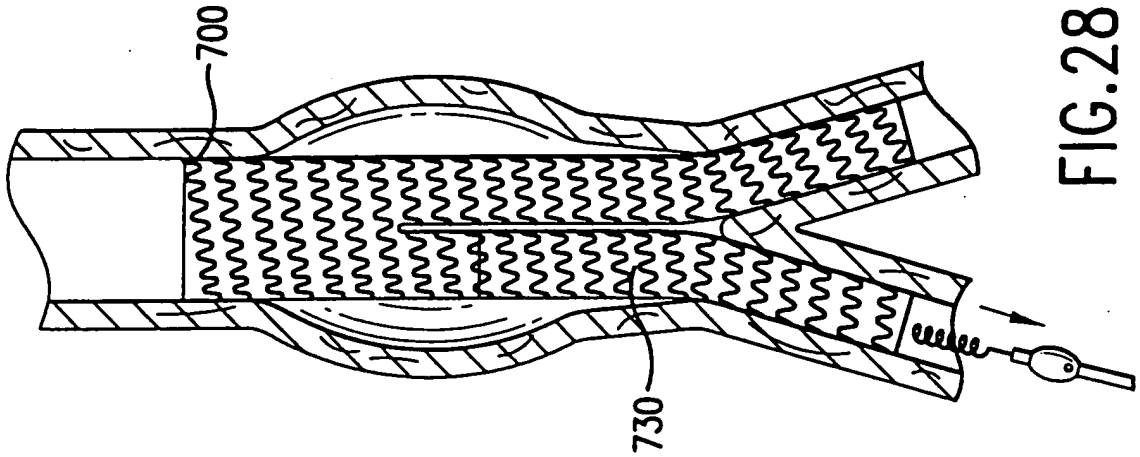


FIG.28E

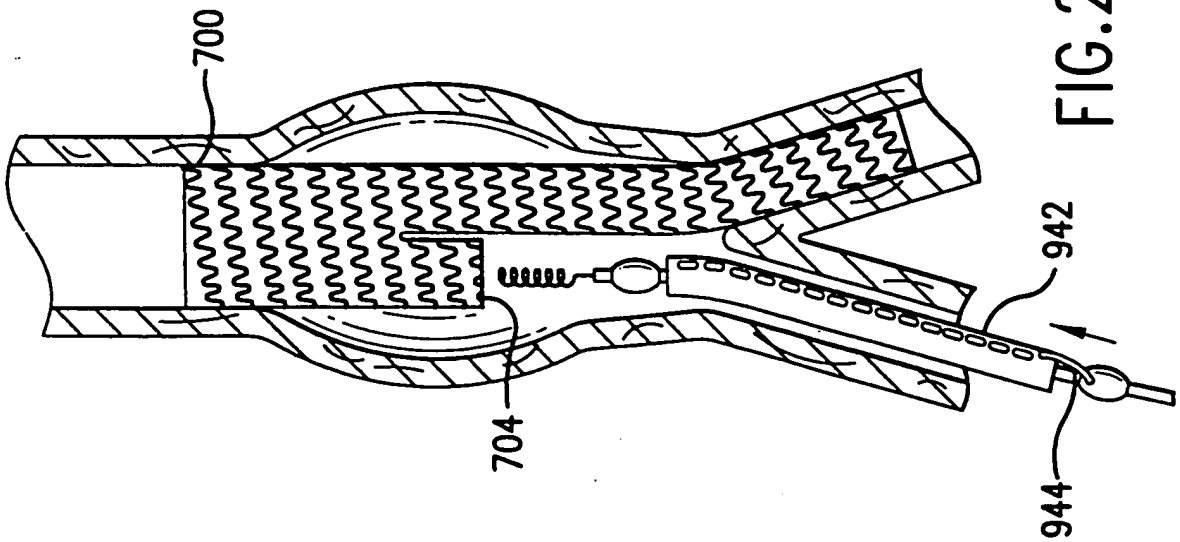


FIG.28D

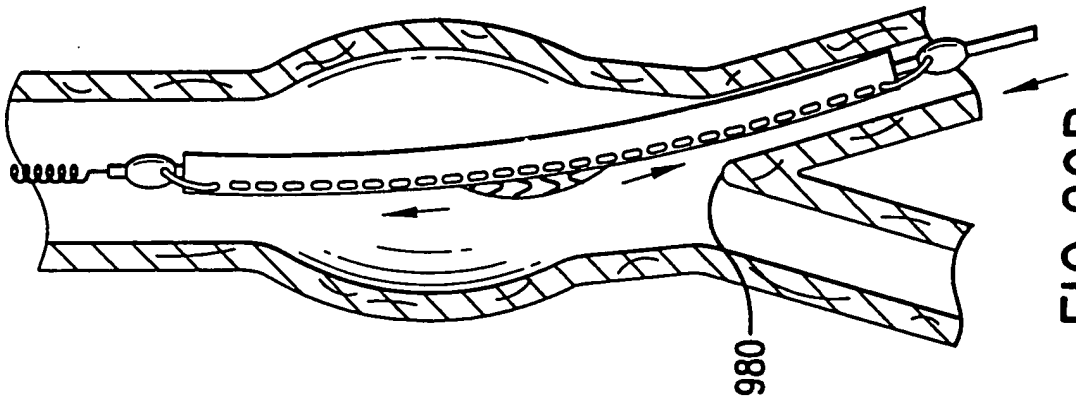


FIG.29B

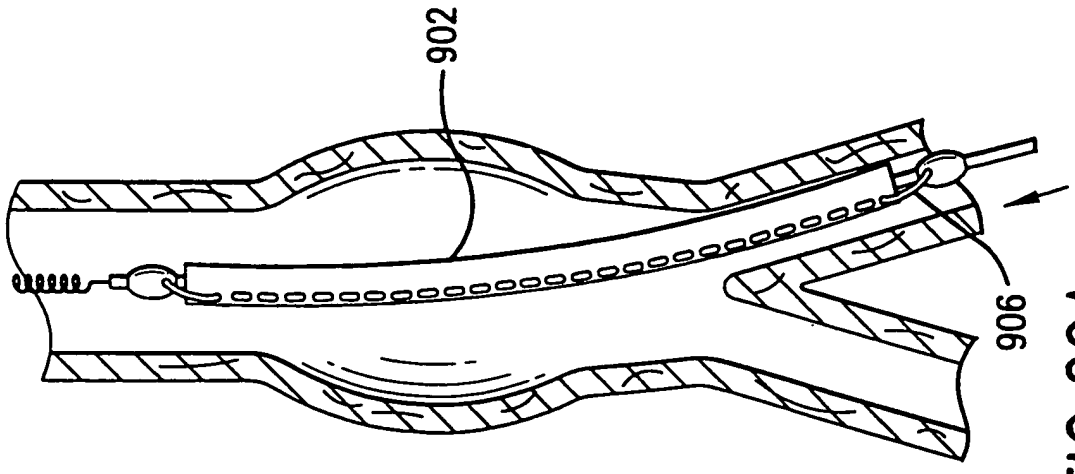


FIG.29A

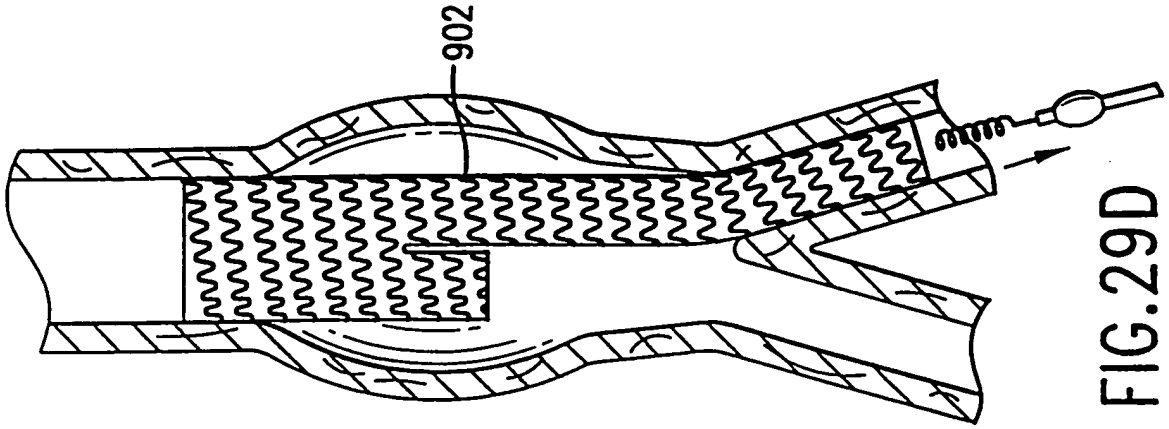


FIG.29D

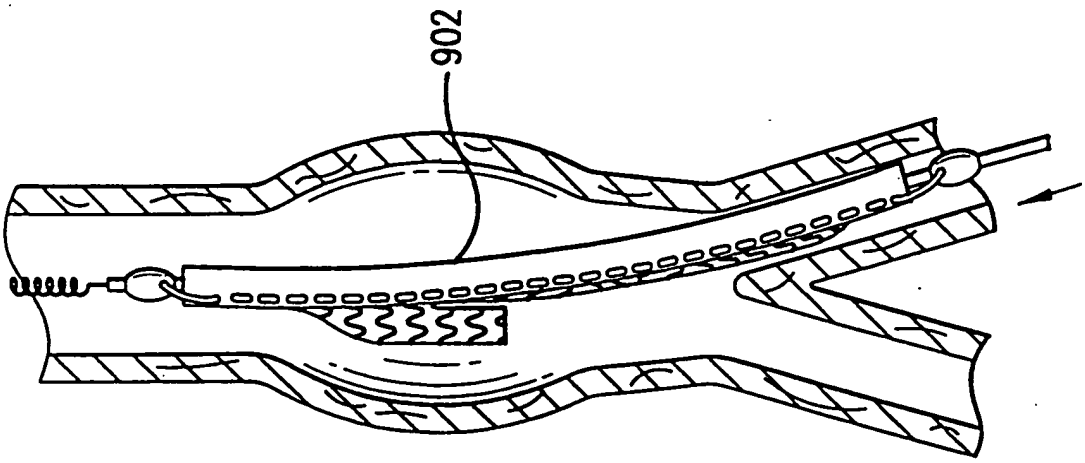


FIG.29C

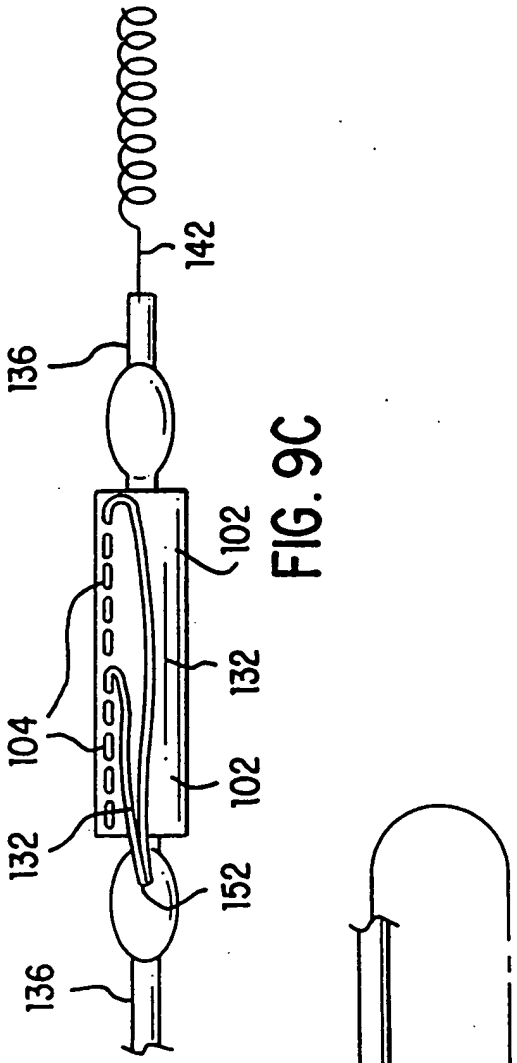


FIG. 9C

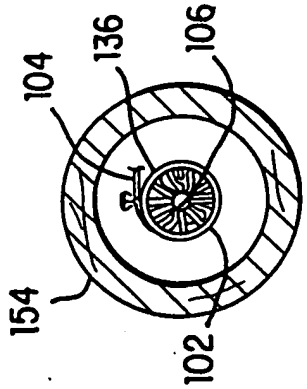


FIG. 9B

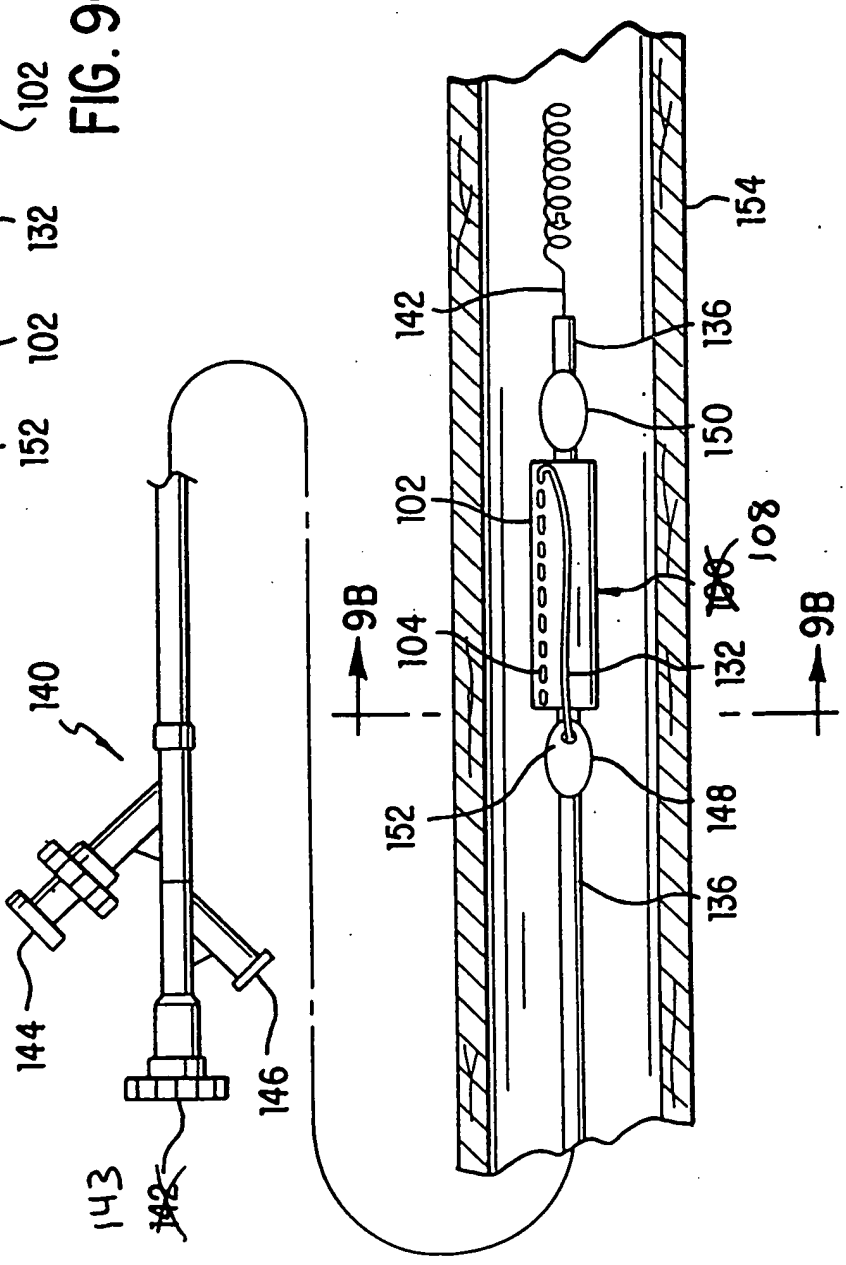


FIG. 9A

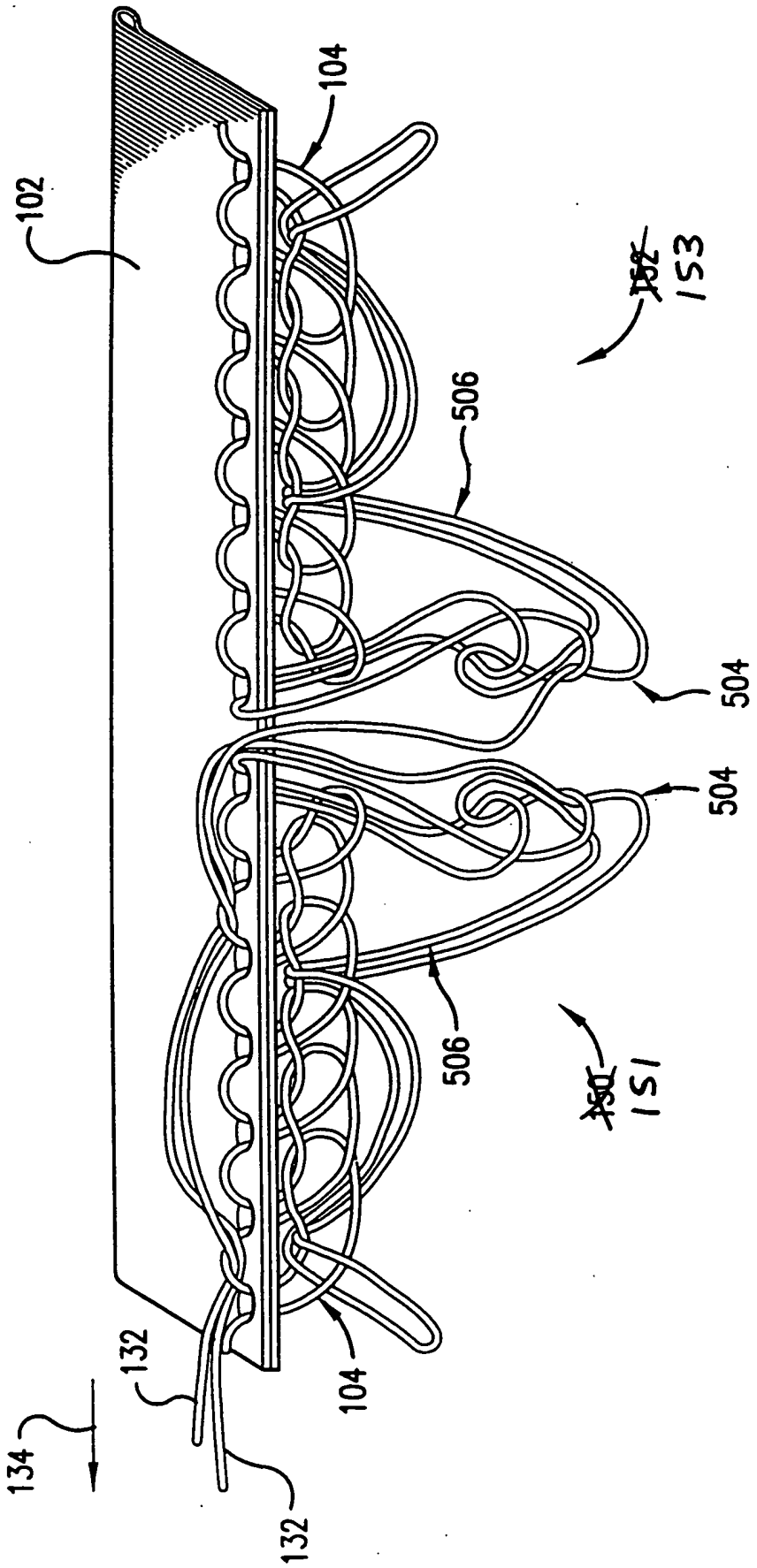


FIG. 13

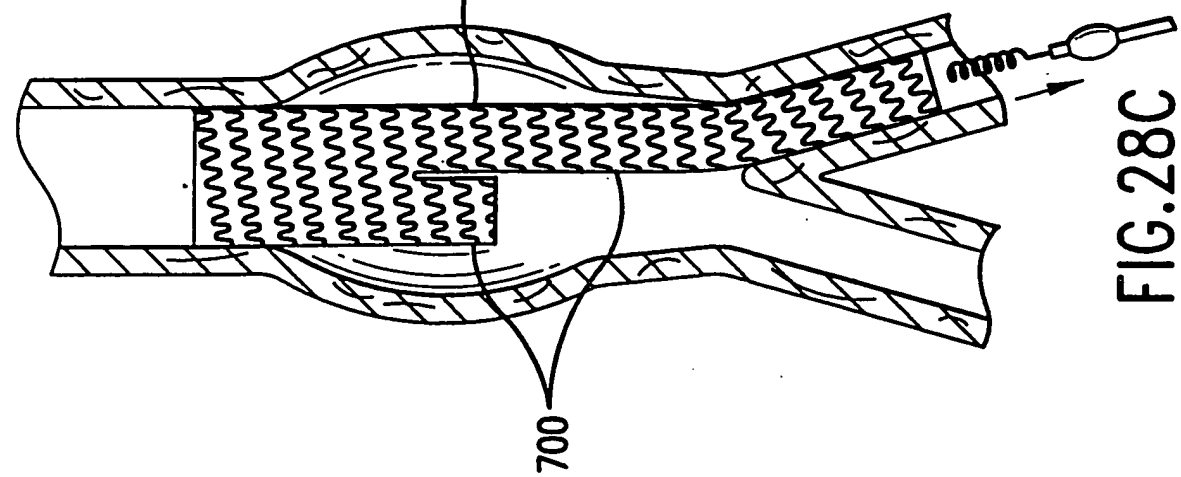


FIG.28C

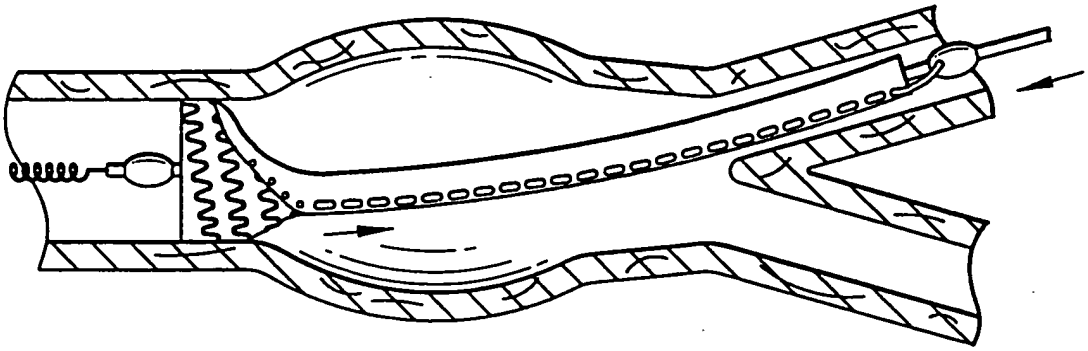


FIG.28B

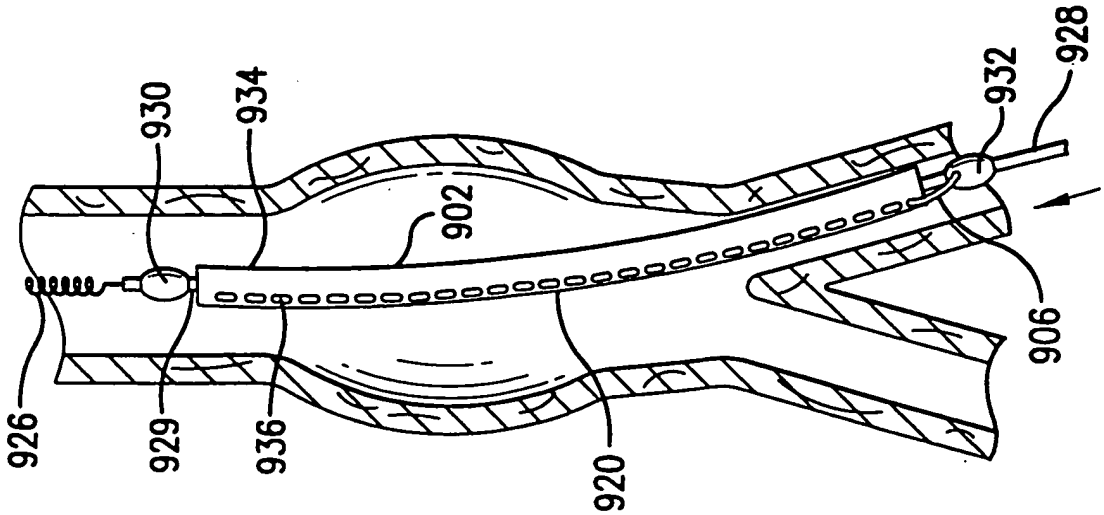


FIG.28A

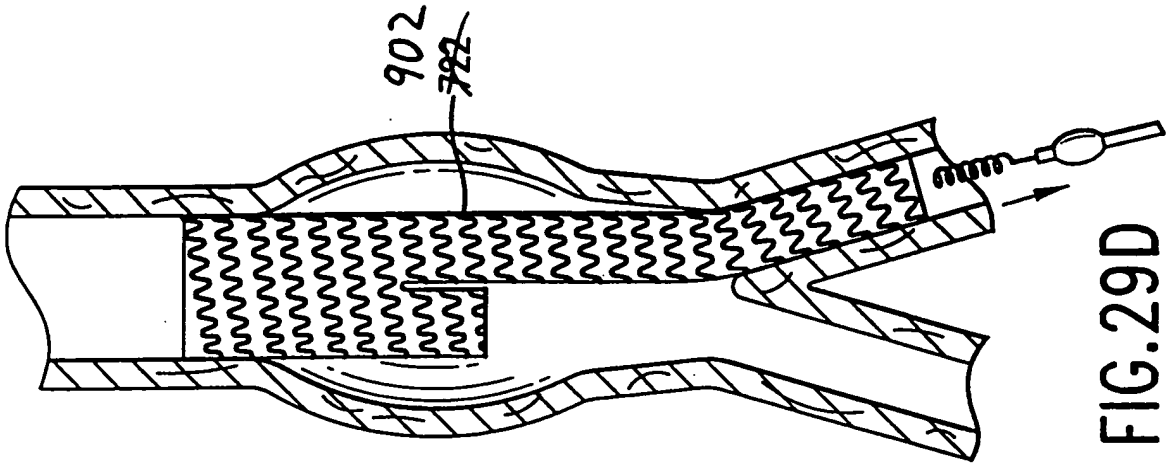


FIG.29D

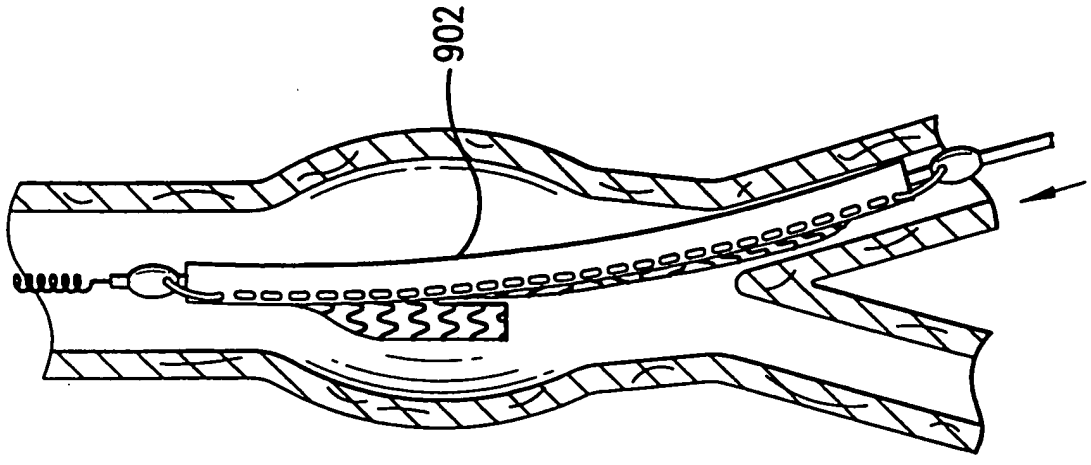


FIG.29C

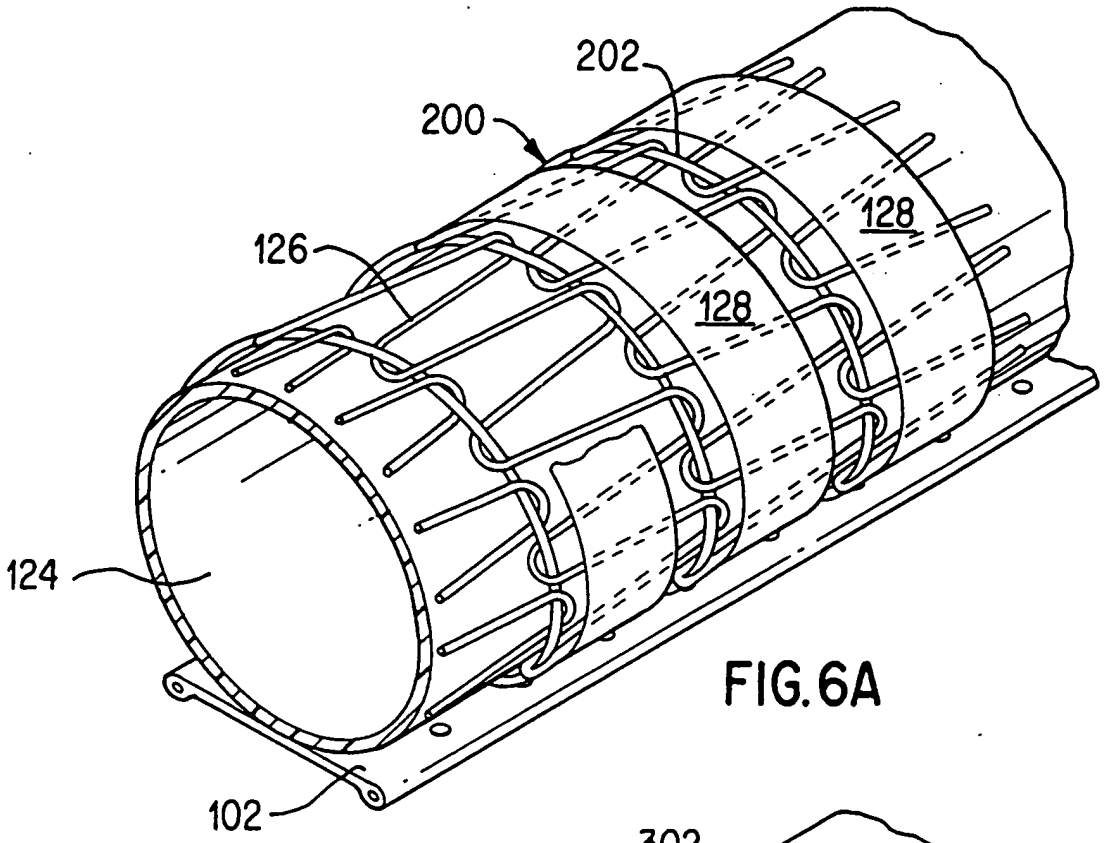


FIG. 6A

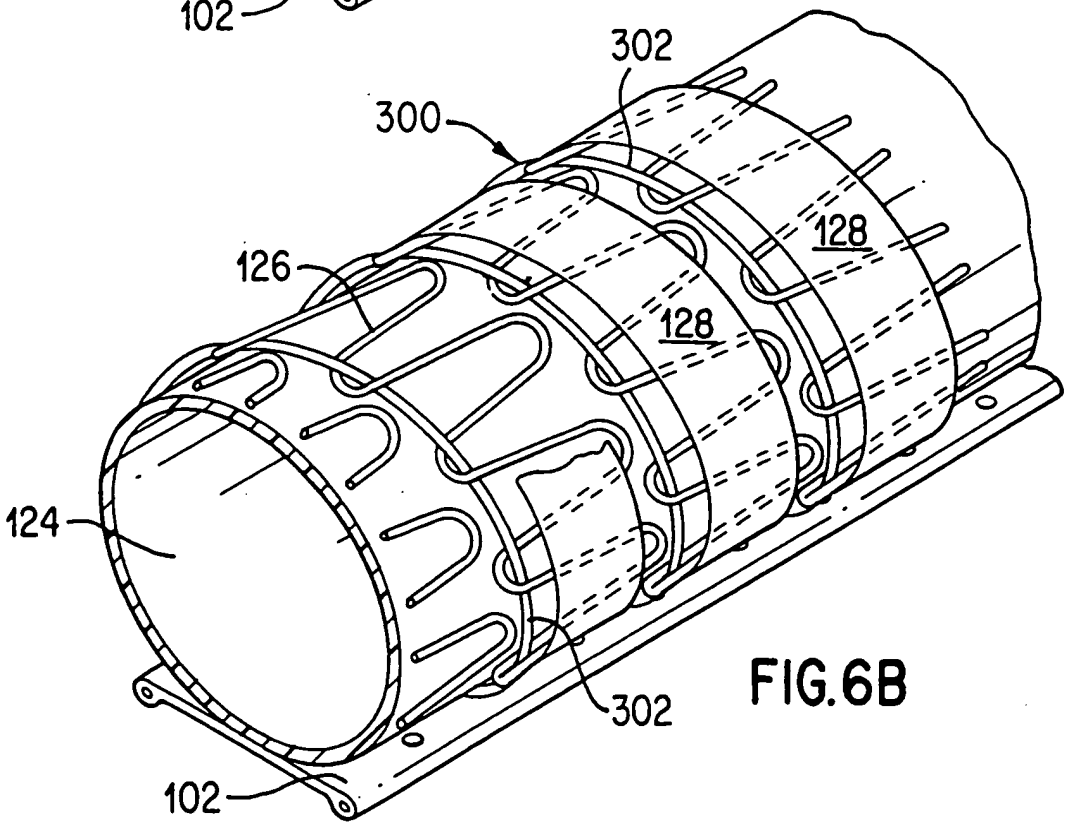


FIG. 6B